KAYE

Advanced Validation System

Kaye Validator AVS

Turn the
page to the
Next Generation...

Advanced Validation Technology

The Kaye Validator AVS (Advanced Validation System) is a state of the art validation system designed to meet current regulatory requirements for Thermal Validation and Data Integrity.

The Validator AVS combines high accuracy measurements, automated sensor calibration, intuitive metro style user interface, and extensive reporting to simplify the complete validation process.

The Validator AVS is the successor of the widely recognized Kaye Validator 2000, the accepted standard in wired validations systems for over 20 years.

- Hardened, Dedicated Validation Console
- Asset Centric Data Management Concept
- Intuitive Metro-Style User Interface

- Enhanced Connectivity
- Increased Scan Speed

Lifting Validation to the Next Level

The Kaye Validator AVS System is a unique design and concept combining a stand-alone Validator AVS along with a Validator AVS Console. The AVS console is a rugged hardened console dedicated to interfacing with your Kaye Validator AVS. It is pre-loaded with the Kaye AVS software and a core load that is dedicated to Validation tasks only. This concept greatly simplifies software validation and dependency on continuously changing PC's, Operating Systems, and core loads.

The Kaye Validator AVS offers easy, dedicated and reliable validation. The AVS is intuitive, efficient, and easy to operate - allowing you to focus on the validation, not the technology.

- Portable Validation Console - Pre-loaded Software
- Dedicated to Validation Tasks
- Simplified Compliance and Easy Validation
- Data Integrity and 21 CFR Part 11 Compliant

- Direct connection via docking mechanism / Wi-Fi and Ethernet
- Console Can be Used to Interface with Multiple AVS Units

- Stand-Alone Operation
- Reliable Data Safety by Smart Redundancy Concept
- Battery Backup 3 Hours

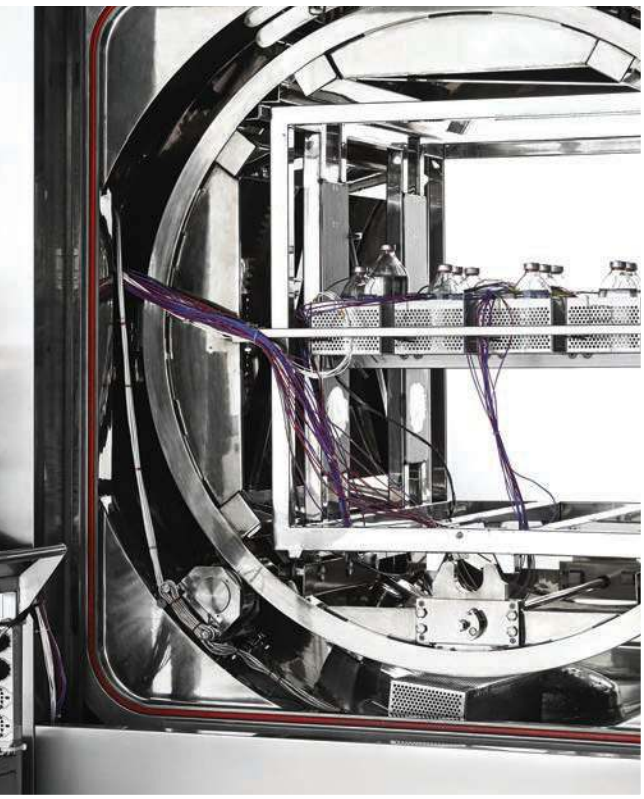
Applications - Challenges - Solutions

Applications

- Steam Sterilizers (Autoclaves)
- Dry Heat Sterilizers
- Steam in Place (SIP)
- Water Cascade/Fall Sterilizers
- Incubators
- Stability Chambers
- Freezers
- Freeze Dryer/Lyophilisation
- Vessels

Challenges

- Pharmaceutical industries are faced
- **IT Environment**
  - Increased IT security and lock do
  - Continually changing operation sy
    - Hardware compatibility
    - Complex software operation
- **Validation**
  - Diverse evolution of technologies
    - Data backward compatibility
  - Complex and time consuming data
    - Cost and time of validation and



Solutions

- Kaye Validator AVS Console dedicated for validation
- OS and Hardware controlled and validated by Kaye
- Eliminates IT control
- Intuitive metro-style touch screen interface
- Simplified Validation
- Asset Centric Data Management concept
- Data Integrity / 21 CFR part 11 compliant

with increasing operational challenges

wn on portable data
ystems

in validation

a organization
re-validation

Kaye Validator AVS

AVS System

A Kaye Validator AVS system consists of the Validator AVS and the Validation Console. The console can be docked directly to the Validator AVS and is used as the operator interface to the Validator AVS.

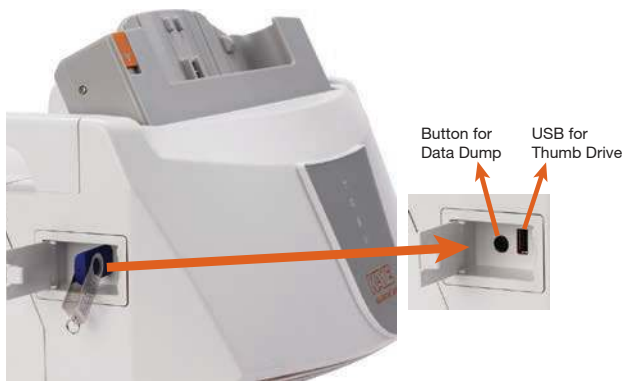
Selectable input capacity (1 to 4 SIMs) up to 48 total inputs.

Robust Design

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

Data Security via Smart Redundancy Concept

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



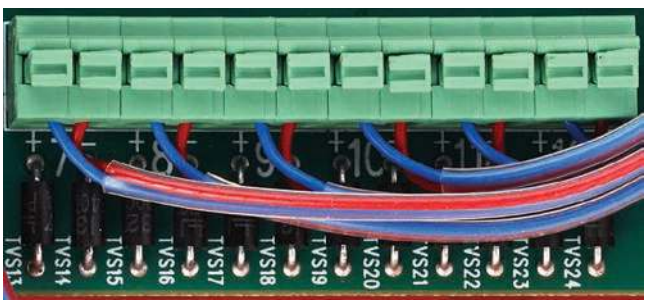
Hardware Connectivity

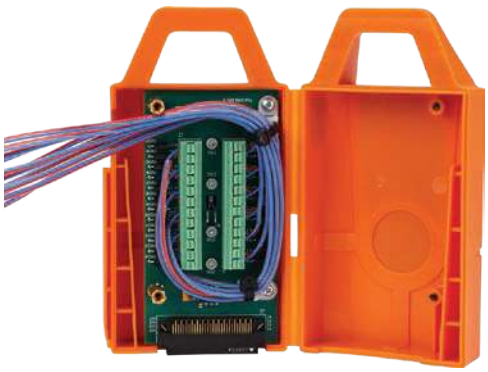
The Kaye Validator AVS comes complete with improved robust connections for IRTD and Calibration Baths. The Validator AVS is backward compatible with all existing IRTD and Kaye Baths for Automatic Calibration. Two relay outputs are also available to be activated via Qualification events.

The Validator has 4 slots on the back of the unit for easy plug-in of SIMs

Sensor Inputs

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





Kaye Validation Console

A New Flexible Approach to Validation

The Kaye Validator AVS Console is a state-of-the-art, portable and rugged console dedicated to the programming, displaying, reporting, and storage of Validator AVS data. The Console comes pre-loaded and configured with the Kaye AVS software and is customized to specific Validation tasks.

The Console offers direct docking and Wi-Fi connectivity with the Validator AVS; it brings about a new approach to tackling your Software Validation.

Validation Console Specifications

Processor

Intel® Core™ Processor

Durability

IP54 rated

- Water, Dust and Splash resistant
- Durable Gorilla® Glass
- Rubberized for shock dampening
- Molded Handle to prevent drops

Display

10.4“ Display with Projective Capacitive Dual Touch Gorilla Glass

System Storage

mSATA Solid State Drive (SSD)

Integrated Communications

Intel® Centrino® Advanced-N 6235

IEEE 802.11a/b/g/n Wi-Fi®

Separate Docking Station Available

I/O Ports

Docking Connector

USB 3.0 port with rubberized cover

Embedded I/O

On-Board Camera capability of taking pictures with Console

Dimensions / Weight

10.0“ x 10.0“ x .95“ (256mm x 256mm x 24.3mm)

3.3 lbs (1,50 kg) [1]

Battery

Battery life up to 6 hours [2]

1. Weight represents approximate system weight measured with a 40WHr battery. Actual system weight may vary depending on component and manufacturing variability.
2. Battery life varies by configuration, applications in use, utilized features and operating conditions. Maximum battery capacity decreases with time and use.

Two ways to Connect the Validation Console to the Kaye Validator AVS

1 Docking Mode
(Standalone)

The console sits in the docking station of the Validator AVS and connects directly.

The Validator AVS offers a fully functional docking station with direct access to the ports located on rear of the unit.

Console battery is charged while docked.

2 Network Mode

The Validator AVS and the console can connect to a local network by using Ethernet or Wi-Fi connection.

One validation console can handle multiple Kaye Validator AVS‘s simultaneously.

The Kaye Validator AVS system can establish wireless connections* by utilizing any kind of available Wi-Fi infrastructure like in-house Wi-Fi access points or simply set up a smartphone as a hotspot. This feature simplifies your daily routine work. You can access the live data wirelessly on the console screen while the Validator is wired on the other side of the autoclave. You can start or stop studies and read the live data from a Kaye Validator AVS in a cleanroom without entering the room.

* This feature is not available in some countries. Please contact your local Kaye support for details.

Kaye Validator AVS Software

Asset Centric Data Management

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

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

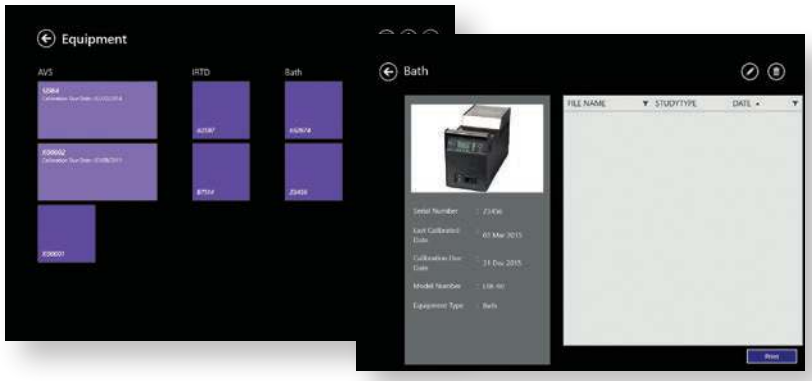
- Organized Study Data
- Simplified Data Search

Equipment Assets

The Kaye Validator AVS also allows you to define assets for each piece of Kaye Validation equipment. Data such as serial number, calibration due dates can be defined. The software will automatically notify user when calibrations are due.

The equipment search function uses the Kaye serial number, that is automatically retrieved as part of the study file*, to find related files. With just one fingertip you get a list of qualification studies, where the equipment asset was used.

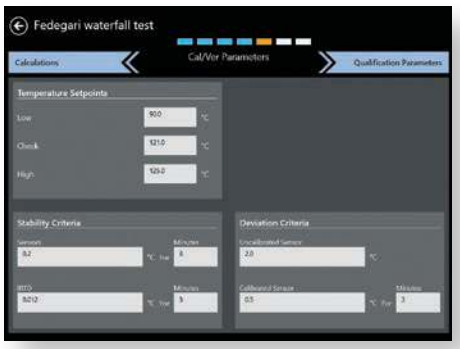
* not for Temperature bath product line



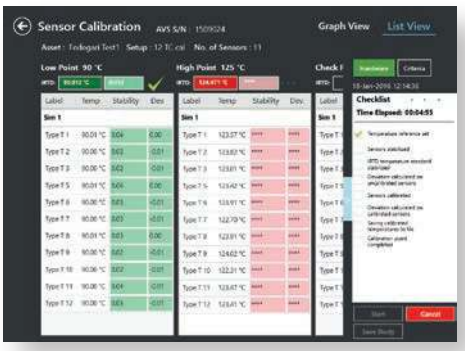
Sensor Calibration

Kaye the original creator of the Automatic Sensor Calibration feature has included enhancements eliminating manual methods of sensor calibration resulting in better accuracy. The Kaye Validator AVS is backward compatible to existing Kaye IRTD and Calibration baths. The Automatic Calibration feature minimizes training and ensure accurate, and repeatable calibrations optimized for your Kaye calibration equipment

Select only the sensors you want to calibrate. Defining a calibration set lets you calibrate any number of sensors among all those wired to the system.



Set the criteria for a sensor calibration - low, high and check point for the actual calibration.

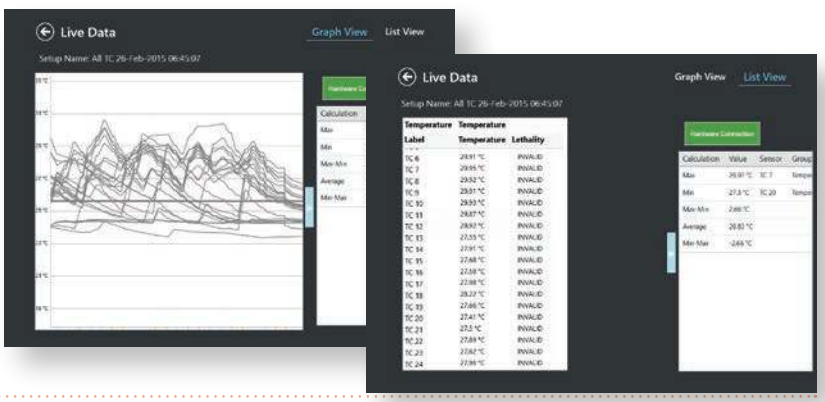


The Console shows the entire calibration process on one screen. Data fields change color to show the progress of stability and deviation for each sensor. A status screen lists each step and indicates where the system is in the process.

Hardware

The Kaye Validation console can connect to a Validator AVS directly through the docking port of the AVS or any network based connection available. It enables the user to transfer setups, start studies and monitor live data or read finished studies. After the start a study, the Validator AVS runs the tasks independently. One Kaye Validation console can control several Validator AVS in parallel and one Validator AVS can handle several consoles. That means you can disconnect and work with a different Validator AVS.

While connected to the Validator AVS the user can see the live data in List or or Layout view, group based calculation and event messages. Any connected hardware is displayed with serial number. Simple color code informs the operator of the calibration status of his sensors and sensor input modules.



Kaye AVS Reporting Tool

Document Critical Validation Studies

The Kaye Validator AVS Console includes an extensive and flexible Reporting Tool used to analyze and document your critical Validation studies. The AVS Reporting Tool is a separate application which is seamlessly integrated into the AVS software. It can be used to documnet your Validation studies, as well as provide Pass/Fail Criteria analysis to save hours of manual efforts.

While offering several new features and enhancements, the Reporting Tool is designed to ensure that the proven and accepted formats of the Validator 2000: Summary, Detailed Interval and Calibration reports are maintained, and Calibration formats are maintained.

Enhancements to Graphing reports, Set-up reports, as well as new reports such as Pass/Fail Criteria Report, provide faster and more detailed ways of analyzing your data. Reports can be previewed, printed, saved as a PDF or exported in CSV format.

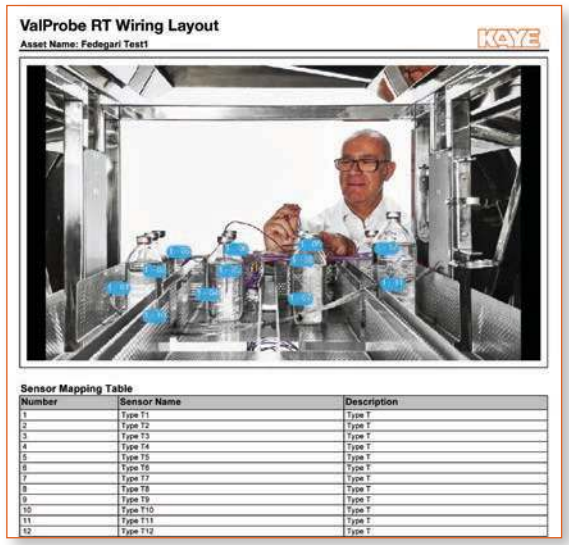
Configuration Choices

Prior to generating reports the AVS Reporting Tool provides a host of configuration choices:

- Sensors Included in Report
- Sensors Separated by Groups
- Sensor Placement and Description
- Define Cycles (Qualification, Exposure, etc)
- Calculations (Statistical, Lethality, Saturation, MKT etc)
- Header / Footers
- Graphing
- Templates with Pass / Fail Criteria analysis

These features provide maximum flexibility to ensure you get the data and calculations you need in the format you need to meet your Validation reporting needs.

Wiring Diagram


ValProbe RT Wiring Layout

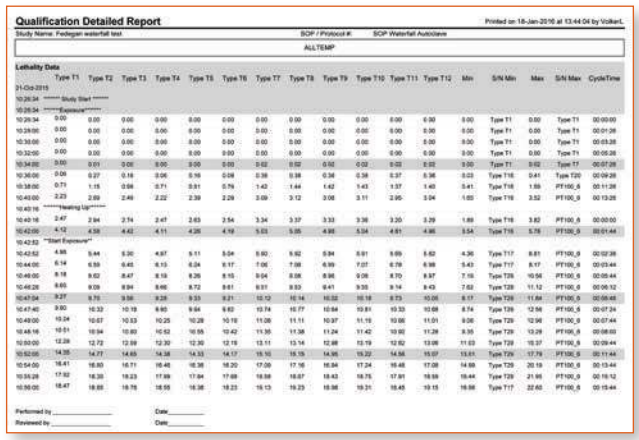
Asset Name: Fedegari Test1

KAYE

Sensor Mapping Table

Number	Sensor Name	Description
1	Type T1	Type T
2	Type T2	Type T
3	Type T3	Type T
4	Type T4	Type T
5	Type T5	Type T
6	Type T6	Type T
7	Type T7	Type T
8	Type T8	Type T
9	Type T9	Type T
10	Type T10	Type T
11	Type T11	Type T
12	Type T12	Type T

Detailed Lethality Report


Qualification Detailed Report

Printed on 18-Jan-2016 at 13:44:04 by VolkerL

Study Name: Fedegari waterfall test

SOP / Protocol #:

SOP Waterfall Autoclave

ALLTEMP

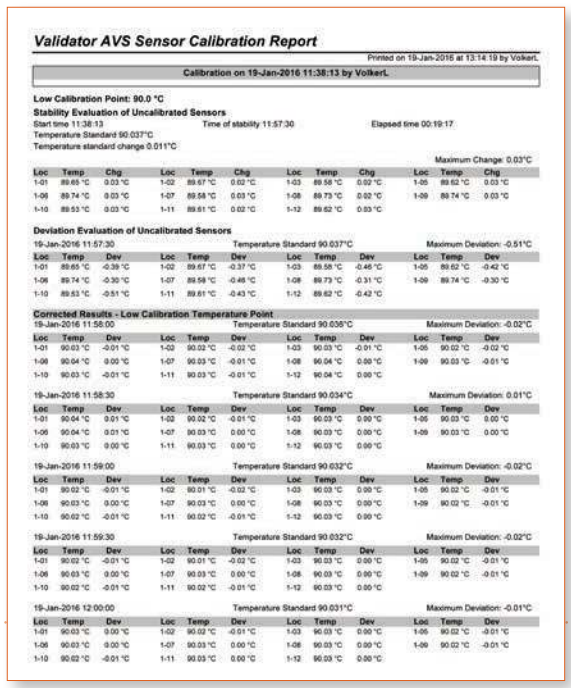
Lethality Data

	Type T1	Type T2	Type T3	Type T4	Type T5	Type T6	Type T7	Type T8	Type T9	Type T10	Type T11	Type T12	Min	S/N Min	Max	S/N Max	CycleTime
21-Oct-2015																	
10:28:34	****** Study Start ******																
10:28:34	****** Exposure******																
10:28:34	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	Type T1	0.00	Type T1	00:00:00
10:28:50	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	Type T1	0.00	Type T1	00:01:26
10:30:00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	Type T1	0.00	Type T1	00:03:26
10:32:00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	Type T1	0.00	Type T1	00:05:26
10:34:00	0.00	0.01	0.00	0.00	0.00	0.02	0.02	0.02	0.02	0.02	0.02	0.00	0.00	Type T1	0.02	Type T7	00:07:26
10:36:00	0.06	0.27	0.16	0.06	0.16	0.08	0.38	0.38	0.36	0.38	0.37	0.36	0.03	Type T16	0.41	Type T20	00:09:26
10:38:00	0.73	1.15	0.88	0.71	0.81	0.76	1.42	1.44	1.42	1.43	1.37	1.40	0.41	Type T16	1.55	PT100_5	00:11:26
10:40:00	2.23	2.69	2.46	2.22	2.39	2.29	3.09	3.12	3.08	3.11	2.95	3.04	1.03	Type T16	3.52	PT100_5	00:13:26
10:40:16	****** Heating Up******																
10:40:18	2.47	2.94	2.74	2.47	2.63	2.54	3.34	3.37	3.33	3.36	3.20	3.29	1.88	Type T16	3.62	PT100_5	00:00:00
10:42:00	4.12	4.58	4.42	4.11	4.26	4.19	5.03	5.05	4.98	5.04	4.81	4.96	3.54	Type T16	5.78	PT100_5	00:01:44
10:42:52	****Start Exposure****																
10:42:52	4.86	5.44	5.30	4.97	5.11	5.04	5.92	5.92	5.94	5.91	5.89	5.82	4.36	Type T17	6.81	PT100_5	00:02:26
10:44:00	6.14	6.59	6.45	6.13	6.24	6.17	7.06	7.08	6.99	7.07	6.79	6.98	5.43	Type T17	8.17	PT100_5	00:03:44
10:46:00	8.18	8.62	8.47	8.19	8.26	8.15	9.04	9.06	8.96	9.06	8.70	8.97	7.19	Type T28	10.56	PT100_5	00:05:44
10:48:28	9.65	9.09	8.94	9.66	8.72	9.61	9.51	9.53	9.41	9.55	9.14	9.43	7.62	Type T28	11.12	PT100_5	00:06:12
10:47:04	9.27	9.75	9.56	9.28	9.33	9.21	10.12	10.14	10.02	10.18	9.73	10.05	8.17	Type T28	11.84	PT100_5	00:08:48
10:47:40	9.80	10.32	10.18	9.80	9.94	9.82	10.74	10.77	10.64	10.81	10.33	10.68	8.74	Type T28	12.56	PT100_5	00:07:24
10:49:00	10.24	10.67	10.53	10.25	10.28	10.19	11.08	11.11	10.97	11.19	10.66	11.01	9.06	Type T28	12.96	PT100_5	00:07:46
10:48:16	10.51	10.94	10.80	10.52	10.55	10.42	11.35	11.38	11.24	11.42	10.90	11.28	9.35	Type T29	13.28	PT100_5	00:08:00
10:50:00	12.28	12.72	12.59	12.30	12.30	12.18	13.11	13.14	12.98	13.19	12.62	13.06	11.03	Type T29	15.37	PT100_5	00:09:44
10:52:00	14.35	14.77	14.65	14.38	14.33	14.17	15.10	15.15	14.95	15.22	14.56	15.07	13.01	Type T29	17.79	PT100_5	00:11:44
10:54:00	16.41	16.80	16.71	16.46	16.36	16.20	17.09	17.16	16.94	17.24	16.48	17.08	14.99	Type T29	20.19	PT100_5	00:13:44
10:55:28	17.92	18.30	18.23	17.99	17.84	17.66	18.58	18.67	18.43	18.75	17.91	18.59	16.44	Type T29	21.66	PT100_5	00:15:12
10:56:00	18.47	18.88	18.78	18.55	18.38	18.23	19.13	19.23	18.98	19.31	18.45	19.15	16.98	Type T17	22.60	PT100_5	00:15:44

Performed by _____ Date_____

Reviewed by _____ Date_____

Calibration Report


Validator AVS Sensor Calibration Report

Printed on 19-Jan-2016 at 13:14:19 by VolkerL

Calibration on 19-Jan-2016 11:38:13 by VolkerL

Low Calibration Point: 90.0 °C

Stability Evaluation of Uncalibrated Sensors

Start time 11:38:13 Time of stability 11:57:30 Elapsed time 00:19:17

Temperature Standard 90.037°C

Temperature standard change 0.011°C

Maximum Change: 0.03°C

Loc	Temp	Chg	Loc	Temp	Chg	Loc	Temp	Chg	Loc	Temp	Chg
1-01	89.65 °C	0.03 °C	1-02	89.67 °C	0.02 °C	1-03	89.58 °C	0.02 °C	1-05	89.62 °C	0.03 °C
1-06	89.74 °C	0.03 °C	1-07	89.58 °C	0.03 °C	1-08	89.73 °C	0.02 °C	1-09	89.74 °C	0.03 °C
1-10	89.53 °C	0.03 °C	1-11	89.61 °C	0.02 °C	1-12	89.62 °C	0.03 °C			

Deviation Evaluation of Uncalibrated Sensors

19-Jan-2016 11:57:30 Temperature Standard 90.037°C Maximum Deviation: -0.51°C

Loc	Temp	Dev	Loc	Temp	Dev	Loc	Temp	Dev	Loc	Temp	Dev
1-01	89.65 °C	-0.39 °C	1-02	89.67 °C	-0.37 °C	1-03	89.58 °C	-0.46 °C	1-05	89.62 °C	-0.42 °C
1-06	89.74 °C	-0.30 °C	1-07	89.58 °C	-0.46 °C	1-08	89.73 °C	-0.31 °C	1-09	89.74 °C	-0.30 °C
1-10	89.53 °C	-0.51 °C	1-11	89.61 °C	-0.43 °C	1-12	89.62 °C	-0.42 °C			

Corrected Results - Low Calibration Temperature Point

19-Jan-2016 11:58:00 Temperature Standard 90.038°C Maximum Deviation: -0.02°C

Loc	Temp	Dev	Loc	Temp	Dev	Loc	Temp	Dev	Loc	Temp	Dev
1-01	90.03 °C	-0.01 °C	1-02	90.02 °C	-0.02 °C	1-03	90.03 °C	-0.01 °C	1-05	90.02 °C	-0.02 °C
1-06	90.04 °C	0.00 °C	1-07	90.03 °C	-0.01 °C	1-08	90.04 °C	0.00 °C	1-09	90.03 °C	-0.01 °C
1-10	90.03 °C	-0.01 °C	1-11	90.03 °C	-0.01 °C	1-12	90.04 °C	0.00 °C			

19-Jan-2016 11:58:30 Temperature Standard 90.034°C Maximum Deviation: 0.01°C

Loc	Temp	Dev	Loc	Temp	Dev	Loc	Temp	Dev	Loc	Temp	Dev
1-01	90.04 °C	0.01 °C	1-02	90.02 °C	-0.01 °C	1-03	90.03 °C	0.00 °C	1-05	90.03 °C	0.00 °C
1-06	90.04 °C	0.01 °C	1-07	90.03 °C	0.00 °C	1-08	90.03 °C	0.00 °C	1-09	90.03 °C	0.00 °C
1-10	90.03 °C	0.00 °C	1-11	90.03 °C	0.00 °C	1-12	90.03 °C	0.00 °C			

19-Jan-2016 11:59:00 Temperature Standard 90.032°C Maximum Deviation: -0.02°C

Loc	Temp	Dev	Loc	Temp	Dev	Loc	Temp	Dev	Loc	Temp	Dev
1-01	90.02 °C	-0.01 °C	1-02	90.01 °C	-0.02 °C	1-03	90.03 °C	0.00 °C	1-05	90.02 °C	-0.01 °C
1-06	90.03 °C	0.00 °C	1-07	90.03 °C	0.00 °C	1-08	90.03 °C	0.00 °C	1-09	90.02 °C	-0.01 °C
1-10	90.02 °C	-0.01 °C	1-11	90.02 °C	-0.01 °C	1-12	90.03 °C	0.00 °C			

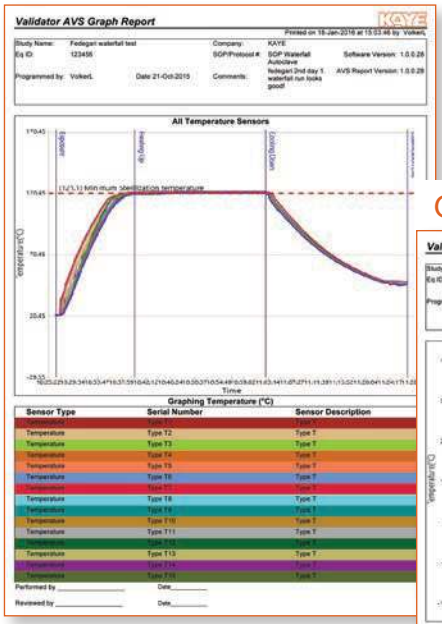
19-Jan-2016 11:59:30 Temperature Standard 90.032°C Maximum Deviation: -0.02°C

Loc	Temp	Dev	Loc	Temp	Dev	Loc	Temp	Dev	Loc	Temp	Dev
1-01	90.02 °C	-0.01 °C	1-02	90.01 °C	-0.02 °C	1-03	90.03 °C	0.00 °C	1-05	90.02 °C	-0.01 °C
1-06	90.03 °C	0.00 °C	1-07	90.03 °C	0.00 °C	1-08	90.03 °C	0.00 °C	1-09	90.02 °C	-0.01 °C
1-10	90.02 °C	-0.01 °C	1-11	90.02 °C	-0.01 °C	1-12	90.03 °C	0.00 °C			

19-Jan-2016 12:00:00 Temperature Standard 90.031°C Maximum Deviation: -0.01°C

Loc	Temp	Dev	Loc	Temp	Dev	Loc	Temp	Dev	Loc	Temp	Dev
1-01	90.03 °C	0.00 °C	1-02	90.02 °C	-0.01 °C	1-03	90.03 °C	0.00 °C	1-05	90.02 °C	-0.01 °C
1-06	90.03 °C	0.00 °C	1-07	90.03 °C	0.00 °C	1-08	90.03 °C	0.00 °C	1-09	90.02 °C	-0.01 °C
1-10	90.02 °C	-0.01 °C	1-11	90.03 °C	0.00 °C	1-12	90.03 °C	0.00 °C			

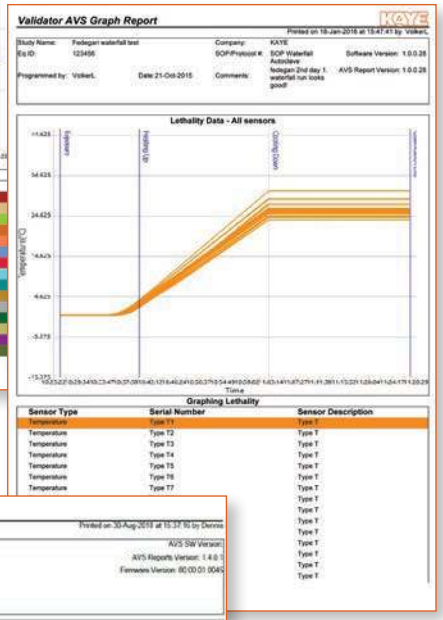
Graph Report


Validator AVS Graph Report

All Temperature Sensors

Graphing Temperature (°C)

Graph Lethality Report

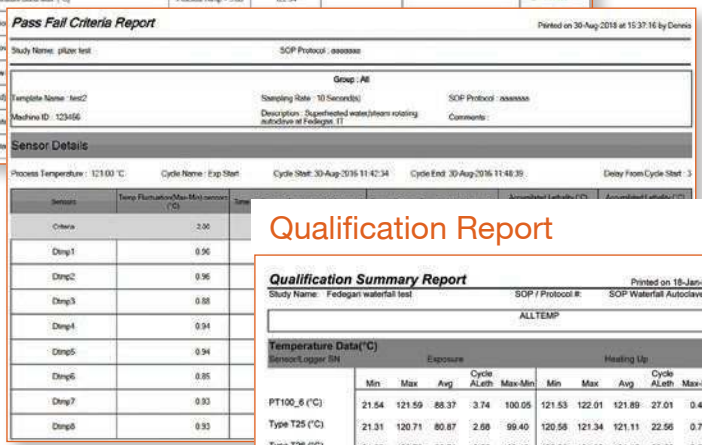

Validator AVS Graph Report

Lethality Data - All sensors

Graphing Lethality

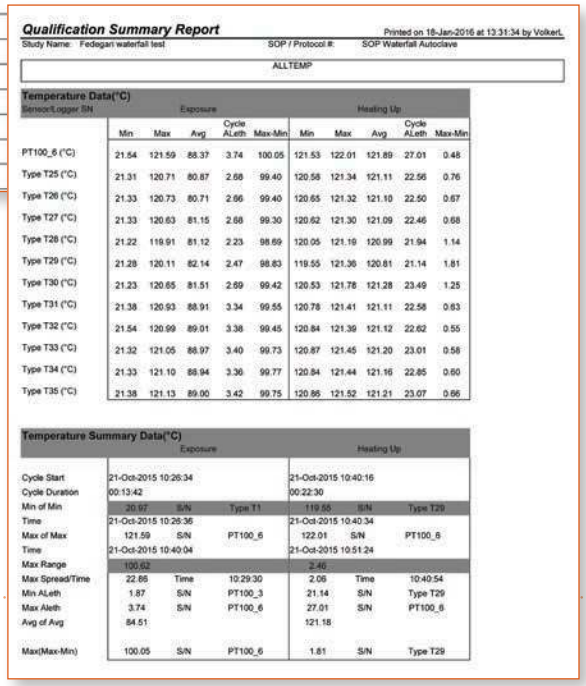
Pass / Fail Report


Pass Fail Criteria Report


Pass Fail Criteria Report

Sensor Details

Qualification Report


Qualification Summary Report

Temperature Data(°C)

Temperature Summary Data(°C)

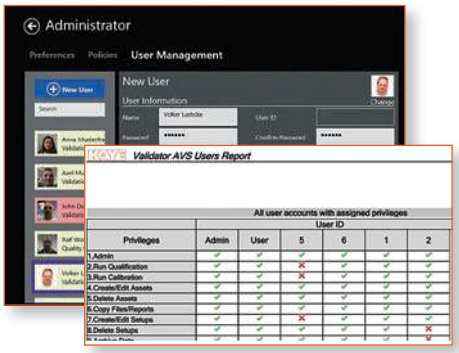
Reporting

- AVS Wiring Layout
- Setup Report
- Calibration Report
- Graph Report
- Detailed Report:
  - Statistical
  - Lethality
  - Saturation
  - MKT
- Summary Report
- Verification Report
- Pass / Fail Criteria Report
- Audit Trail Report

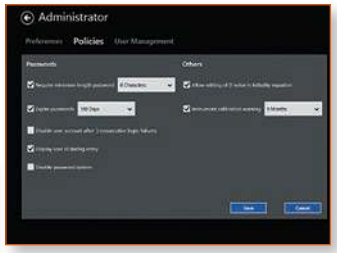
Data Integrity / 21 CFR Part 11 Compliance

The Validator AVS was designed to meet the current regulatory guidelines for Data Integrity and 21 CFR Part 11. From the design of the Validation Console which minimizes operator access to files to the automated Sync functions to provide secure back up of the files. The system was designed to provide ease of use while in the background providing the data management and security to meet regulatory guidelines. All of these functionalities are fully documented in our Data Integrity and 21 CFR Part 11 Assesment documents.

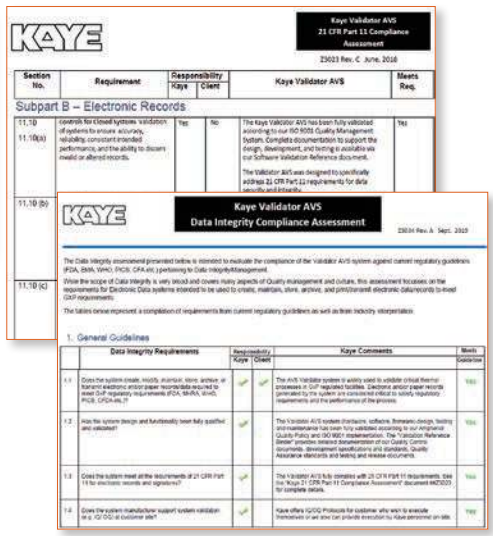
User Management



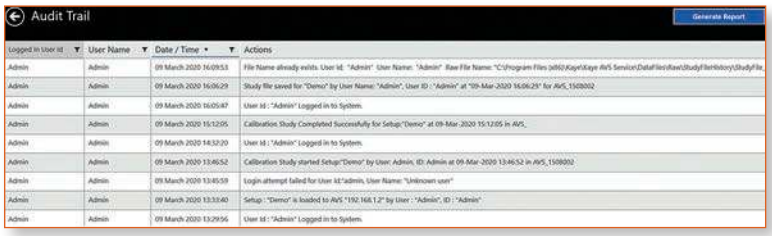
Policies



Data Integrity Compliance



Audit Trail Report



The Kaye Validator AVS is specifically designed to enable compliance with FDA 21 CFR Part 11. All recorded data, including calibration offsets, set-up parameters, and administrative tasks are saved in secure, encrypted, tamper-proof electronic records in a format accessible only through the system software. In addition to pre-configured privilege levels, it is possible to explicitly set permissions for each user.

With data synchronization to a shared folder it is possible to exchange configuration and data files like your assets, setups and study files with other Kaye Validation consoles. It also allows to synchronize the user database but also merging the audit trails of several consoles enabling sorting, searching and printing of department-wide audit trails, for example, a list of all failed login attempts within a specified time period across all synchronized Kaye Validation consoles. Every console has a unique but customizable machine ID for identification.

Calibration / Verification

High Accuracy Referencing

Kaye's temperature calibration equipment is designed specifically to maximize overall system accuracy. Calibration equipment includes temperature references with superior uniformity for sensors, traceable intelligent RTD standards, and validation software to communicate with the hardware.

Intelligent RTD Standard

The IRTD Temperature Standard (IRTD-400) is a NIST-traceable instrument that is calibrated over the range of -195°C to 420°C. It is accurate to ±0.025°C over the entire operating range.

The IRTD-400 is a completely self-contained measurement system, containing the electronics for calibration and temperature conversion.

Communicating directly with the Validator software, the IRTD-400 eliminates the potential for human error, assuring accurate and traceable measurements.

Fast/Accurate References

One temperature reference covers the temperature range for the high and low calibration point used for a typical validation study. Choose the model that best fits your need from the chart below.

Temperature dry wells employ unique inserts that minimize cooling of the thermocouple tips due to stem conduction. Without proper inserts, transfer uncertainty in excess of 0.5°C can occur with 22 gage, type T thermocouples. Amphenol units provide an uncertainty of 0.1°C.

Calibrating over a more limited range will also increase accuracy. Since regulations require calibration for the temperature range of a process, an autoclave, for example, can be calibrated from 90°C to 125°C. This method reduces the error from thermocouple characteristics to less than 0.05°C—a two-fold improvement over a calibration at 0°C and 125°C.

The temperature bath, CTR-80, provides very fast response (90 minutes from ambient to -80°C) and quiet operation. Rugged casters allow this unit to be moved with little effort. A specially designed cover supports two IRTD standards and all thermocouples from the Kaye Validator AVS.

	CTR-40	CTR-80
Temperature Range	-40 to 150°C	-80 to 100°C
Temperature Stability	±0.005°C to -40°C (ethanol) ±0.005°C to 25°C (eau) ±0.007°C to 150°C (huile 5012)	±0.03°C
Temperature Uniformity	±0.01°C	±0.03°C

	HTR 400	LTR -25/140	LTR-40/140	LTR-90
Temperature Range	25°C above ambient to 400°C	–25°C to 140°C	–40°C to 140°C	–95°C to 140°C
Ambient Operating Range	5°C to 50°C	5°C to 50°C	5°C to 50°C	5°C to 50°C
Set-Point Accuracy	0.2°C to 300°C 0.3°C to 400°C	0.2°C	0.2°C	0.2°C
Temperature Stability	0.02°C to 300°C 0.05°C to 400°C	0.02°C	0.02°C	0.02°C

Accessories

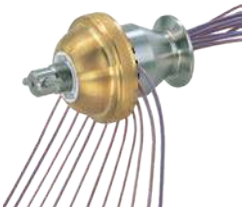
The Kaye product range including moisture meters, testers and sensors are designed to meet the most demanding industrial requirements for process improvement, thermal validation and reporting. Specializing in providing turnkey system solutions and supporting them with unmatched technical service, we offer a complete range of temperature standards, baths, thermocouples and fittings, all designed to provide the most accurate process measurement available.

The Kaye product range is relied upon by the world's leading pharmaceutical and biotechnology companies to validate and monitor critical sterilization processes as required by governing regulatory bodies.

- Thermocouples for Autoclaves
- Thermocouples for Dry Heat Tunnels
- Thermocouples: Stainless Steel
- Thermocouples with Stainless Steel Tip

Thermocouples

Kaye thermocouple wire is manufactured with the highest purity and uniformity available to the industry. Quality control and testing of every wire spool and thermocouple probe ensures consistent measurement results. Each spool of wire includes a Certificate of Conformance — your guarantee that it meets the accuracy specifications. Each Teflon® Thermocouple is leakage vacuum tested.



Feed-thru for Autoclave Applications

Easy way to seal the autoclave port when introducing thermocouples into the chamber. Standard 1.5" TRI-CLAMP® process connection. Installation is simple with out the need of any tools, fitted with safety release mechanism.

Pressure Transducer for Autoclaves

Comply with current standards to measure pressure in parallel to temperature when qualifying autoclaves. The pressure sensor is optimized to work with autoclaves and the Validator® AVS.

Shipping Case

Protect your Validator AVS during transfer and shipping and store it safely when not being used.

Cables

System Documentation

Quality Control Documents
Kaye's quality policy, the ISO 9001 implementation and certificate, and document control standard operating procedures (SOPs)

Development Procedures
Design control and project management SOPs, and functional specifications

Quality Assurance Procedures
Test plan and test case procedures

Release Documents
Quality assurance certification and product release notices

Quality Assurance Test Documentation
Quality assurance test plan and test cases

IQ/OQ Protocol

The Installation Qualification/Operational Qualification Protocol defines a set of procedures to ensure that the Kaye Validator AVS system is properly installed and operated according to Amphenol recommendations, and is adequately documented and controlled according to cGMP requirements. The documents are provided in hard copy and on CD, allowing users to modify the documentation to suit specific organizational requirements.

The IQ/OQ Protocol includes the following:

- Installation Qualification document
- Operational Qualification document - AVS
- Operational Qualification document – AVS Report
- Standard Operating Procedures document

If you prefer to have IQ/OQ executed by qualified Kaye technicians we also provide Validation IQ/OQ On-Site Execution.

Validation Reference

The Kaye Validator AVS system is supported with documentation that verifies a fully validated system, including software, hardware and firmware. The Validation Reference Binder provides a comprehensive overview of the Amphenol Quality Policy, description of ISO 9001 implementation and support procedures, and standards for the development, testing, and maintenance of hardware and software. Quality Control documents, Development procedures, Quality Assurance procedures, Release documents, and Quality Assurance test documentation are all included.

The Validation Reference is a serialized document, ensuring that registered users automatically receive notification and updates to keep documentation current. The result is a summary of information you would obtain by conducting an audit at Amphenol's facility—complete, well organized, neatly packaged, and immediately accessible.

Additional Services

- Factory / On-Site System Calibration
- Annual Service Contract
- Rentals

System Specifications

Total System Specifications

When you use specifications to compare equipment, be sure to establish an error budget that accounts for all possible measurement uncertainty. Sensor calibration is an integral part of validation, and total system accuracy should include potential error from the recorder, as well as the temperature reference and traceable standard.

Since all component errors are additive to the total system, every potential error is significant. A summary of the error budget for an Amphenol validation system after sensor calibration with type T thermocouples, used at steam and dry heat, is listed below. These specifications are guaranteed under worst case conditions. Under typical operating conditions, you can expect significantly better accuracy.

Kaye Validator AVS (resolution and short term stability)	0.017°C	k=1
IRTD Temperature Standard	0.01°C	k=1
Temperature Reference	0.051°C	k=1
Total System Uncertainty	0.078°C	k=1

Kaye Validation Specifications

Analog Input	Up to 48
Thermocouples	Type T, J, K,E,B,R,N,S: 0.1°C; T+ limited range 0.01°C resolution
Scanning Speed	48 channels / sec
Internal Memory	4 gb for data collection
Input Impedance	10KΩ. Source greater than 10KΩ produces open circuit indication
Common Mode Rejection	160 db (8 inputs/sec) @ line frequency 145 db (12 inputs/sec) @ line frequency 140 db @ DC
Max. Common Mode Voltage	100V pk ch-to-ch350V pk ch-to ch to frame ground
Normal Mode Rejection	82 db @ 60 Hz (8 inputs/sec)69 db @ 60 Hz (12 inputs/sec)
Voltage Input	0 to 10 VDC
Resolution	1:72,000
Voltage Input Accuracy	30 days: ±(0.003% of reading + 2 counts + 4 microvolts) 1 year: ±(0.006% of reading + 2 counts + 4 microvolts)
Sensitivity	0.5 microvolts/count on most sensitive range
Voltage Temp. Coef.	±(0.1 microvolts + 0.001% reading)/°C
Compensator Temp. Coef.	±0.01°C per °C
Input Terminal Temperature Non-uniformity	±0.1°C from calibrated terminal
Input Ranges	-6 to 30mV, -12 to 60mV, -60 to 300mV, -2 to 10V
Environmental	Temperature: 0 to 50°C (32 to 122°F) Relative humidity: 95% non-condensing
Power	90 to 250 VAC, 50/60 Hz
Fuse Rating	4A Slow Blow
Size	190H X 411W X 381 mm D (457 mm with SIM) 7.5 in H x 16.2 in W x 15 in D (18 in with SIM)
Weight	10.60 kg (23.4 lbs)
Battery	Lithium ion with minimum 3 hours of battery backup

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