KAYE
SUBSIDIARY OF AMPHENOL

Validator® AVS

ADVANCED VALIDATION SYSTEM

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
- 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
- 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 PCs, 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.

Applications – Challenges – Solutions

APPLICATIONS

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

CHALLENGES

- Pharmaceutical industries are faced with increasing operational challenges
- IT environment
  - Increased IT security and lock down on portable data
  - Continually changing operation systems: Hardware compatibility and complex software operation
- Validation
  - Diverse evolution of technologies in validation: Data backward compatibility
- Complex and time consuming data organization
  - Cost and time of validation and re-validation

SOLUTIONS

- Kaye Validator AVS Console dedicated for validation
- OS, core load, and AVS software pre-loaded and tested for maximum reliability and efficiency
- Eliminates IT control
- Powerful and flexible data backup / restore capabilities to meet IT and Data Integrity requirements
- Simplified validation
- Asset centric data management concept
- Data Integrity / 21 CFR part 11 compliant

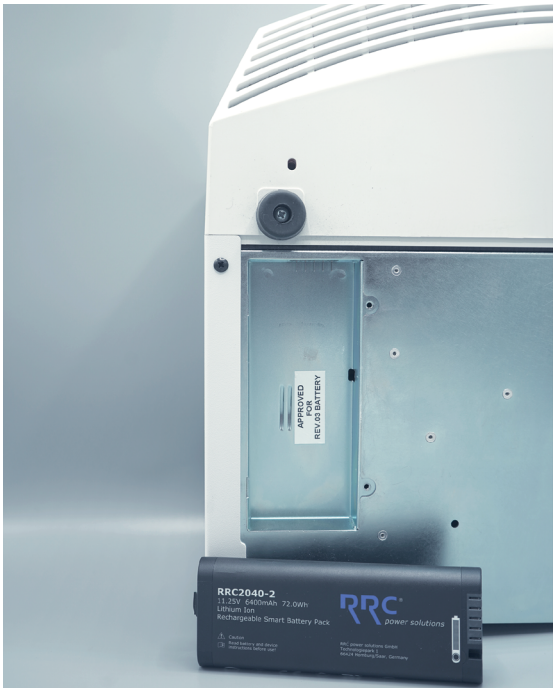
Validator AVS

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
- IP55 rating, chemical resistant ABS housing
- Dedicated Validation Console for improved user interface
- On-board docking station for Kaye Validation Console
- Battery backup with field replaceable battery pack (3 hours)

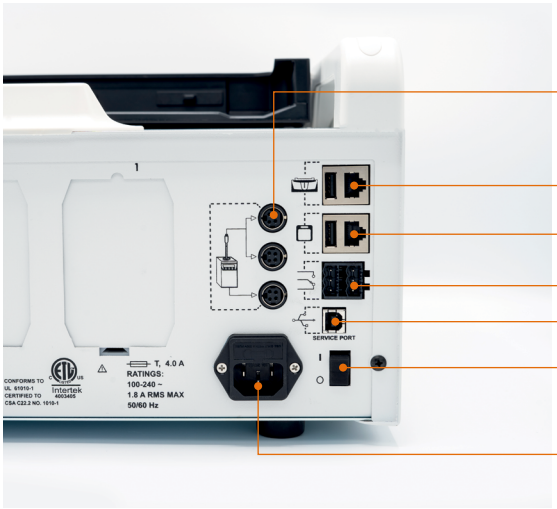


DATA SECURITY VIA SMART REDUNDANCY CONCEPT

- 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

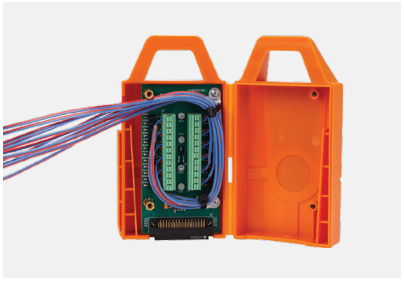
HARDWARE CONNECTIVITY

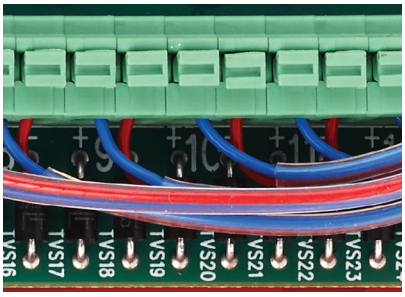
The Kaye Validator AVS comes complete with improved robust connections for IRTD and calibration baths. The Validator AVS is backward compatible with all existing IRTD and Kaye baths for automatic calibration. Two relay outputs are also available to be activated via qualification events.



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

Operating System / Processor / Memory
- Microsoft Windows 10 Enterprise LTSC (64 bit)
- 8th Generation Intel® Core™-i5 Processor
- 8 GB RAM

Durability IP65 Rated
- Military grade durability with improved thermal management
- Maximum protection against dust, dirt, and water ingress
- Drop-tested from 4 feet
- Temperature-tested from -20°F to 145°F (-29°C to 62°C)

Display
- 11.6-inch, FHD 1920 x 1080
- 1000 Nit outdoor-readable
- Anti-glare, anti-smudge, polarizer
- Glove-capable touchscreen

System Storage
- 256GB M.2 Solid State Drive (SSD)

Integrated Communications
- Intel® Wireless-AC 9560
- 802.11ac with Bluetooth 5.0

Separate Docking Station Available

I/O Ports
- Docking Connector
- 1 - USB 3.1 Type-A with power delivery
- 1 - USB 3.0 Type-C port with DisplayPort Alt Mode / PowerShare
- 1 - Combo mic / headphone jack
- 256GB M.2 Solid State Drive (SSD)

Embedded I/O
- On-board camera capability of taking pictures with console
- 5 MP RGB + IR FHD webcam with privacy shutter / 8 MP rear camera with flash and dual microphone

Dimensions / Weight[1]
- 7.99in x 12.29in x .96in (256mm x 256mm x 24.3mm)
- 2.93 lbs (1.33 kg)(1)

Battery
- Battery life up to 6 hours[2]

Backwards Compatibility
- Can run with Kaye Validator and Kaye ValProbe Software

1. Weight represents approximate system weight measured with a 34WHr 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.

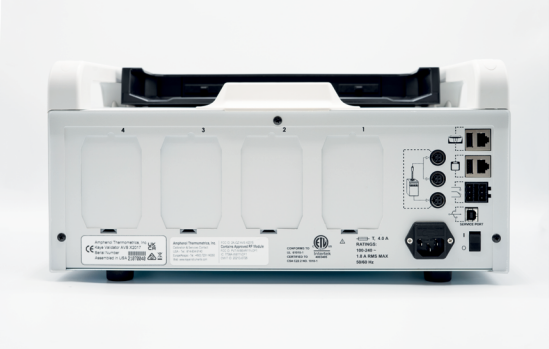
Two ways to Connect the Validation Console to the Validator AVS

1. DOCKING MODE (STAND-ALONE)

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. The Validation Console can be used to communicate to any connected AVS.



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.

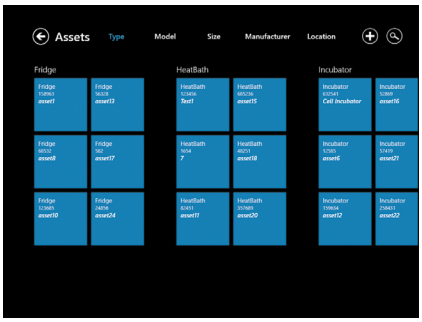
* This feature is not available in some countries. Please contact your local Kaye support for details.

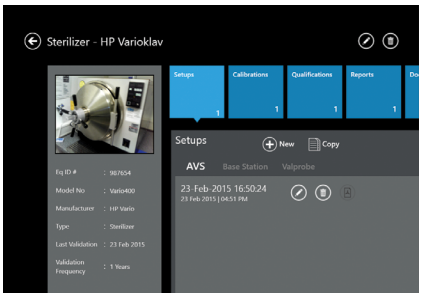
Validator AVS Software

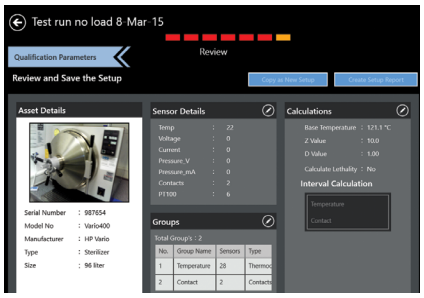
ASSET CENTRIC DATA MANAGEMENT

The Kaye Validator AVS includes an intuitive Asset Centric Data Management concept 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.

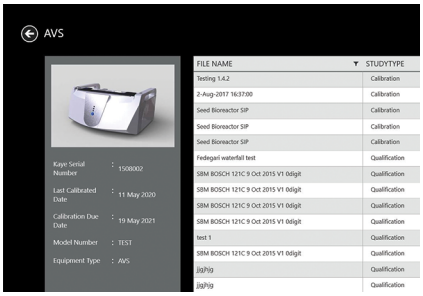






EQUIPMENT ASSETS

The Kaye Validator AVS also allows you to define assets for each piece of Kaye validation equipment. Data such as serial number and 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.

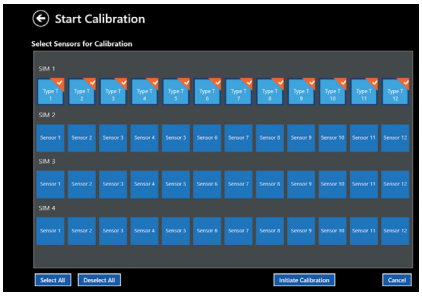


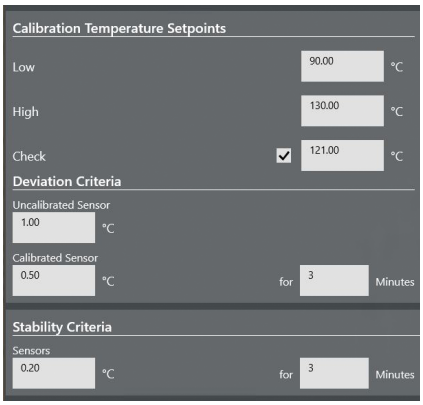
* not for Temperature bath product line

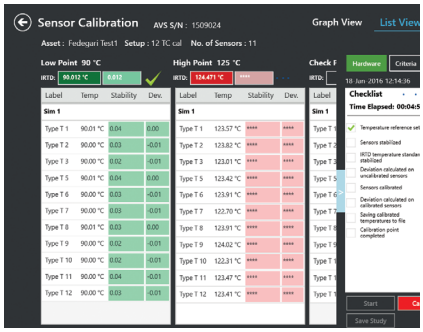
SENSOR CALIBRATION / VERIFICATION

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

Define the temperature setpoint as well as criteria for stability and deviation.





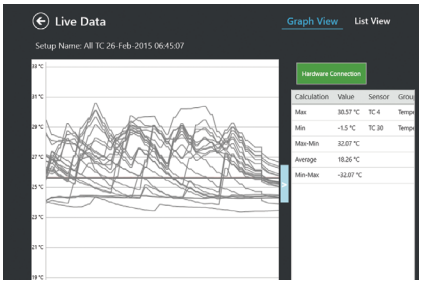


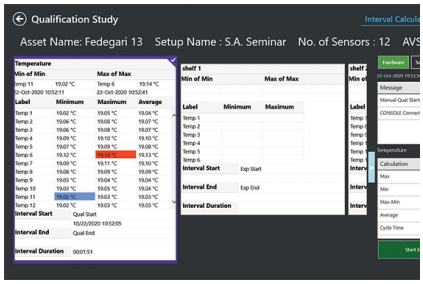
The Console shows the entire calibration process on one screen. Data fields change color to show the progress of stability and deviation for each sensor. A status screen lists each step and indicates where the system is in the process.

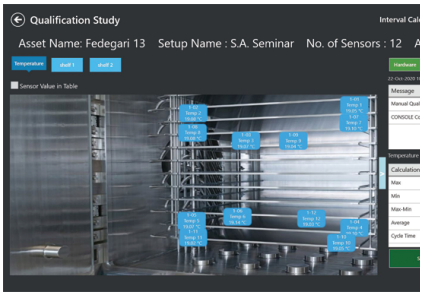
QUALIFICATION STUDY

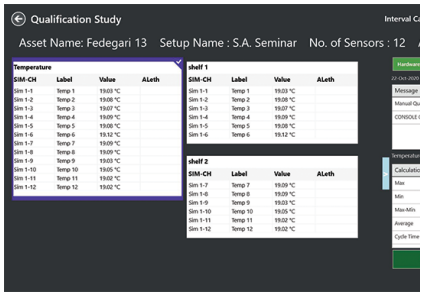
During the Qualification study real-time data can be displayed in multiple formats to easily view and analyze process performance. Views include group-based data, calculations and system messages. Graphical and wiring overlay displays provide additional perspective.

Since the AVS controls the measurement, calculations, and data storage, it is not necessary to have the console connected during the entire study. Users can disconnect the console to go execute a calibration on another AVS. At any time they can return and re-connect the console to the AVS. All of the live and historical information from the AVS can be displayed and analyzed.









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 document 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

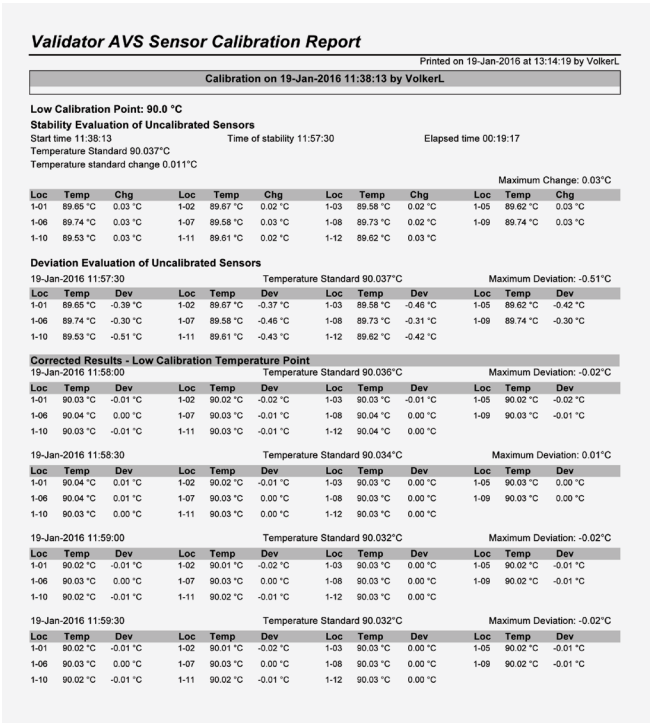
Prior to generating reports the Reporting Tool provides a host of configuration choices:

- 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
- Pass/fail criteria

These features provide you with maximum flexibility to get the data and calculations you require in the correct formats to meet your Validation reporting needs.

REPORTING

- AVS Wiring Layout
- Setup Report
- Calibration Report
- Verification Report
- Graph Report
- Summary Report
- Detailed Report:
  - Statistical
  - Lethality
  - Saturation
  - MKT
- Audit Trail Report
- Pass/Fail Criteria 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 90.036°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			

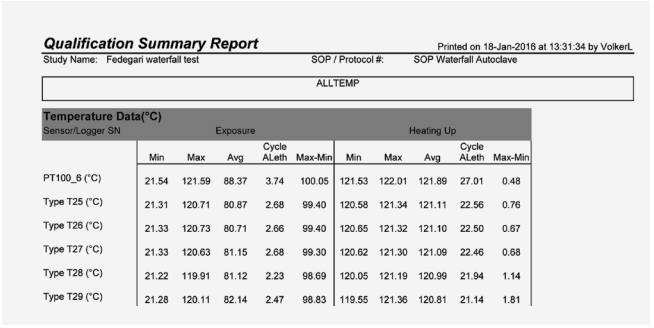
19-Jan-2016 11:59:00 Temperature Standard 90.032°C Maximum Deviation: -0.02°C

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			

Calibration Report



Qualification Summary Report

Printed on 18-Jan-2016 at 13:31:34 by VolkerL

Study Name: Fedegari waterfall test SOP / Protocol #: SOP Waterfall Autoclave

ALLTEMP

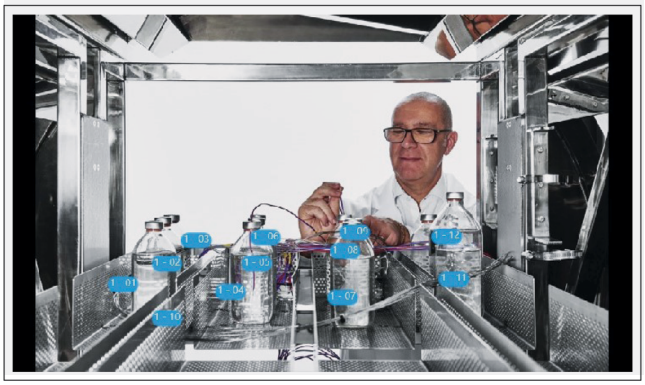
Temperature Data(°C)

Sensor/Logger SN	Exposure					Heating Up				
	Min	Max	Avg	Cycle ALeth	Max-Min	Min	Max	Avg	Cycle ALeth	Max-Min
PT100_6 (°C)	21.54	121.59	88.37	3.74	100.05	121.53	122.01	121.89	27.01	0.48
Type T25 (°C)	21.31	120.71	80.87	2.68	99.40	120.58	121.34	121.11	22.56	0.76
Type T26 (°C)	21.33	120.73	80.71	2.66	99.40	120.65	121.32	121.10	22.50	0.67
Type T27 (°C)	21.33	120.63	81.15	2.68	99.30	120.62	121.30	121.09	22.46	0.68
Type T28 (°C)	21.22	119.91	81.12	2.23	98.69	120.05	121.19	120.99	21.94	1.14
Type T29 (°C)	21.28	120.11	82.14	2.47	98.83	119.55	121.36	120.81	21.14	1.81

Qualification Report

ValProbe RT Wiring Layout

Asset Name: Fedegari Test1



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

Wiring Diagram

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																	
10:26:34	****** Study Start ******																
10:26:34	******Exposure******																
10:26:34	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
10:28:00	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	00:01:26
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	0.00	0.02	0.02	0.02	0.02	0.02	0.02	0.00	Type T1	0.02	Type T7	00:07:26
10:36:00	0.06	0.27	0.18	0.06	0.16	0.09	0.38	0.36	0.38	0.38	0.37	0.38	0.03	Type T16	0.41	Type T20	00:09:26
10:38:00	0.71	1.15	0.98	0.71	0.91	0.79	1.42	1.44	1.42	1.43	1.37	1.40	0.41	Type T16	1.59	PT100_6	00:11:26
10:40:00	2.23	2.69	2.49	2.22	2.39	2.29	3.09	3.12	3.08	3.11	2.95	3.04	1.65	Type T16	3.52	PT100_6	00:13:26
10:40:16	******Heating Up******																
10:40:16	2.47	2.94	2.74	2.47	2.63	2.54	3.34	3.37	3.33	3.36	3.20	3.29	1.89	Type T16	3.82	PT100_6	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_6	00:01:44
10:42:32	******Start Exposure******																
10:42:32	4.98	5.44	5.30	4.97	5.11	5.04	5.90	5.92	5.84	5.91	5.85	5.82	4.36	Type T17	6.81	PT100_6	00:02:36
10:44:00	6.14	6.59	6.45	6.13	6.24	6.17	7.06	7.06	6.99	7.07	6.78	6.98	5.43	Type T17	8.17	PT100_6	00:03:44
10:46:00	8.18	8.62	8.47	8.19	8.26	8.15	9.04	9.06	8.96	9.08	8.70	8.97	7.19	Type T29	10.56	PT100_6	00:05:44
10:46:28	8.65	9.09	8.94	8.66	8.72	8.61	9.51	9.53	9.41	9.55	9.14	9.43	7.62	Type T29	11.12	PT100_6	00:06:12
10:47:04	9.27	9.70	9.56	9.28	9.33	9.21	10.12	10.14	10.02	10.18	9.73	10.05	8.17	Type T29	11.84	PT100_6	00:06:48
10:47:40	9.90	10.32	10.18	9.90	9.94	9.82	10.74	10.77	10.64	10.81	10.33	10.68	8.74	Type T29	12.56	PT100_6	00:07:24
10:48:00	10.24	10.67	10.53	10.25	10.28	10.16	11.08	11.11	10.97	11.15	10.66	11.01	9.08	Type T29	12.96	PT100_6	00:07:44
10:48:16	10.51	10.94	10.80	10.52	10.55	10.42	11.35	11.38	11.24	11.42	10.92	11.28	9.35	Type T29	13.28	PT100_6	00:08:00
10:50:00	12.28	12.72	12.59	12.30	12.30	12.16	13.11	13.14	12.98	13.19	12.62	13.06	11.03	Type T29	15.37	PT100_6	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_6	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_6	00:13:44
10:55:28	17.92	18.30	18.23	17.99	17.84	17.68	18.58	18.67	18.43	18.75	17.91	18.59	16.44	Type T29	21.95	PT100_6	00:15:12
10:56:00	18.47	18.85	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_6	00:15:44

Detailed Lethality Report

Pass Fail Criteria Report

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

Study Name: pfizer test | SOP Protocol : aaaaaaa

Group : All

Template Name : test2 | Sampling Rate : 10 Second(s) | SOP Protocol : aaaaaaa

Machine ID : 123456 | Description : Superheeted water(steam rotating autoclave at Fedegari, IT | Comments :

Sensor Details

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

Sensors	Temp Fluctuation(Max-Min) sensors (°C)	Time >= Process Temperature (hh:mm:ss)	Time < Process Temperature (hh:mm:ss)	Accumulated Lethality (°C) (cycle)	Accumulated Lethality (°C) (study)
Criteria	2.00	Min-00:00:00	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

Pass / Fail Report

Validator AVS Graph Report

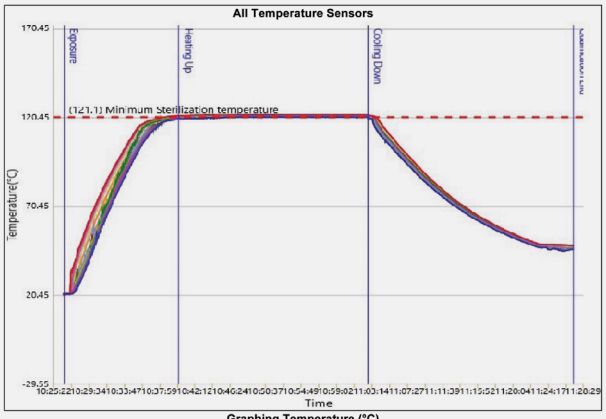
Printed on 18-Jan-2016 at 15:03:46 by VolkerL

Study Name:	Fedegari waterfall test	Company:	KAYE
Eq ID:	123456	SOP/Protocol #:	SOP Waterfall Autoclave
Programmed by:	VolkerL	Date:21-Oct-2015	Comments: fedegari 2nd day 1. waterfall run looks good!

Software Version: 1.0.0.28

AVS Report Version: 1.0.0.28

All Temperature Sensors



Graphing Temperature (°C)

Sensor Type	Serial Number	Sensor Description
Temperature	Type T1	Type T
Temperature	Type T2	Type T
Temperature	Type T3	Type T
Temperature	Type T4	Type T
Temperature	Type T5	Type T
Temperature	Type T6	Type T
Temperature	Type T7	Type T
Temperature	Type T8	Type T
Temperature	Type T9	Type T
Temperature	Type T10	Type T
Temperature	Type T11	Type T

Graph Report

Validator AVS Graph Report

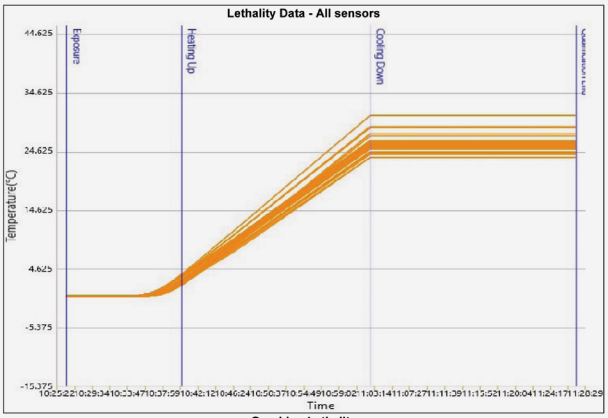
Printed on 18-Jan-2016 at 15:47:41 by VolkerL

Study Name:	Fedegari waterfall test	Company:	KAYE
Eq ID:	123456	SOP/Protocol #:	SOP Waterfall Autoclave
Programmed by:	VolkerL	Date:21-Oct-2015	Comments: fedegari 2nd day 1. waterfall run looks good!

Software Version: 1.0.0.28

AVS Report Version: 1.0.0.28

Lethality Data - All sensors



Graphing Lethality

Sensor Type	Serial Number	Sensor Description
Temperature	Type T1	Type T
Temperature	Type T2	Type T
Temperature	Type T3	Type T
Temperature	Type T4	Type T
Temperature	Type T5	Type T
Temperature	Type T6	Type T

Graph Lethality Report

Pass/Fail Report

When performing a qualification study and collecting raw data, one of the most time consuming tasks is the post-analysis of the data to ensure the study meets all of the required criteria.

For many customers this entails exporting the raw data to excel and using customized pivot tables or macros to analyze the data and create the final report. While this method has been widely used for years, regulatory and validation issue such as 21 CFR and Data Integrity have brought about additional concerns and effort.

To eliminate many of these concerns the AVS software now includes a powerful and flexible Pass/Fail Report which provides immediate indication of study success or failure based on user defined criteria. This report is an efficient and simple way to analyze if a process is within specification while saving hours of post analysis time.

An added benefit to the report is that the complete analysis is done within the AVS software in a secured validated environment. The software directly collects data from the raw encrypted qualification file eliminating the transfer of unprotected files to outside programs. The Pass/Fail report has also undergone extensive testing and validation by Kaye, eliminating the need to validate separate spreadsheets.

Users can select from a list of over 17 different criteria to customize the report to their specific needs and process. The available criteria are based on years of experience as well as numerous regulatory guidelines (i.e. EN285 for sterilization).

In a few easy steps, this tool allows you to define the specific cycle or time period where the data is going to be evaluated. Once you define the time period, users can customize which criteria is applicable for the process and set the criteria parameters. After the parameters are defined, you can save it as a template, saving you time in your future studies. Multiple templates can be set up and saved for different processes and applications.

After setting criteria parameters, users are able to choose which group of sensors the defined criteria should be applied to.

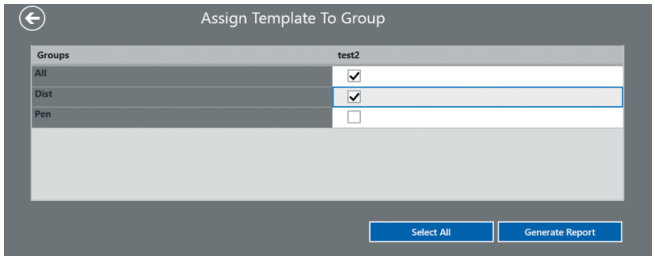
Finally, generate the report and you are immediately provided all the information required for a decision at a glance. All of the information is presented in the validated environment, which saves time, effort, and any additional risk. Having this customizable capability is a huge leap forward in Kaye's enhanced analytics and is just the first phase in our work to streamline the reporting step for our users.

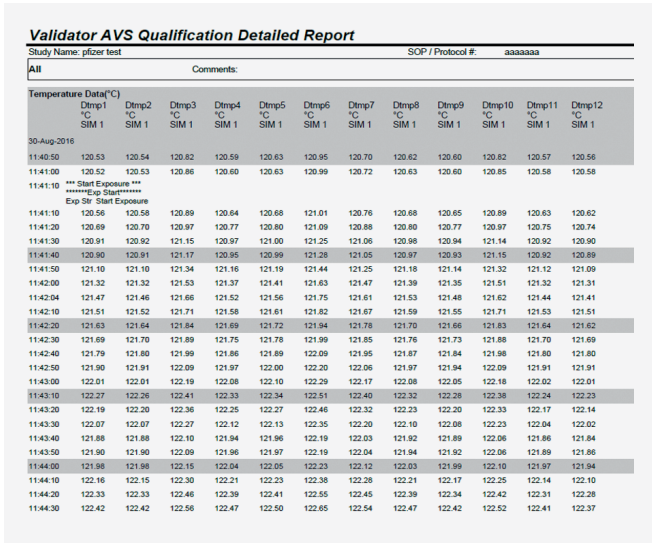
PASS/FAIL REPORT ANALYSIS

The Pass Fail Report is instantly generated and includes the listing of the selected criteria. For each criteria the report includes the name of the criteria, the criteria defined, the calculated value from the analysis as well as the result "Pass/Fail." Additional information given includes the sensor responsible for failure and, if applicable, the time of occurance. From this report the user gets a comprehensive analysis of the study.

PASS/FAIL REPORT BENEFITS

- Immediate indication of qualification success/failure
- Eliminate hours of post analysis
- Provide results in validated software environment
- Flexibility for customer to select and specify criteria based on process, group, and company/regulatory requirements

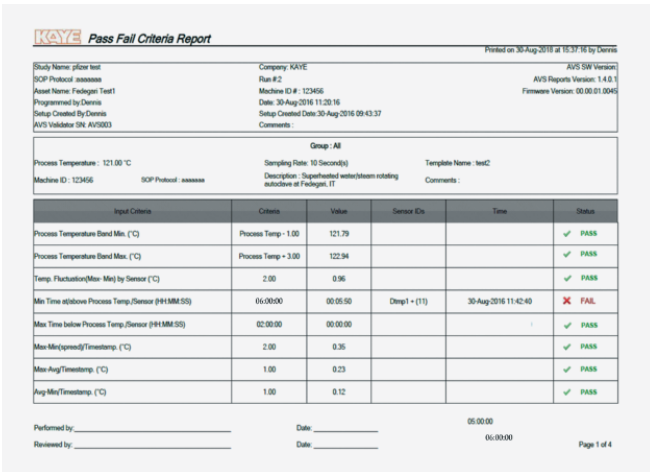


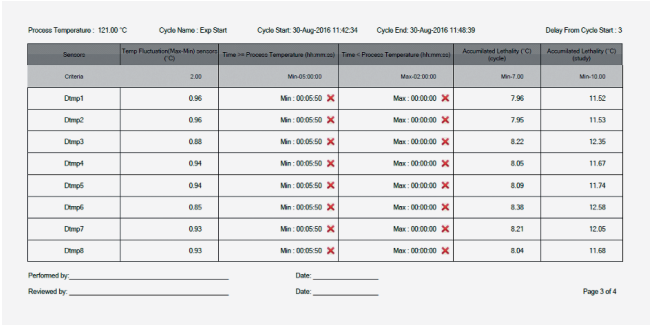


CRITERIA FOR REPORTING

The following criteria are available for selection and setting the specifications for the pass / fail decision:

- Process Temp Band
- Temperature Fluctuation (Max - Min) per Sensor
- Temperature at / above or at / below Process Temp per Sensor
- Group Max - Min (spread) per Timestamp
- Group Max - Average per Timestamp
- Group Average - Min per Timestamp
- Group (Max of Max) – (Min of Min)
- Accumulated lethality
- Temperature – Saturation Temperature Band per Timestamp
- Pressure – Saturation Pressure Band per Timestamp
- Time of Sterilization
- Equilibrium Duration
- Exposure duration / Holding Duration

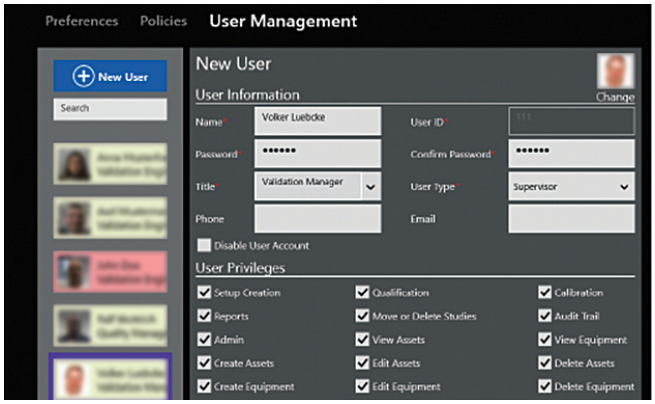




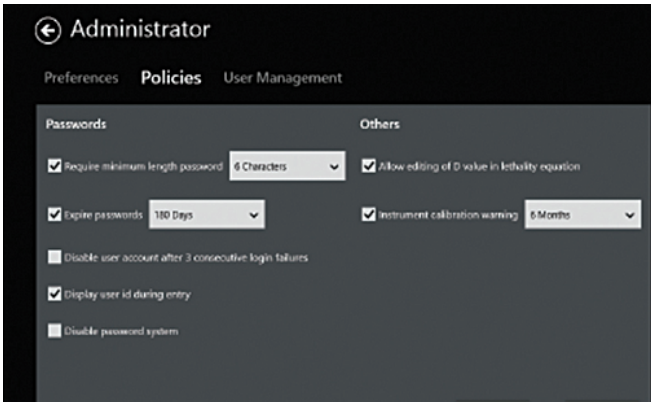
Data Integrity / 21 CFR Part 11 Compliance

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 Assessment documents.
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.

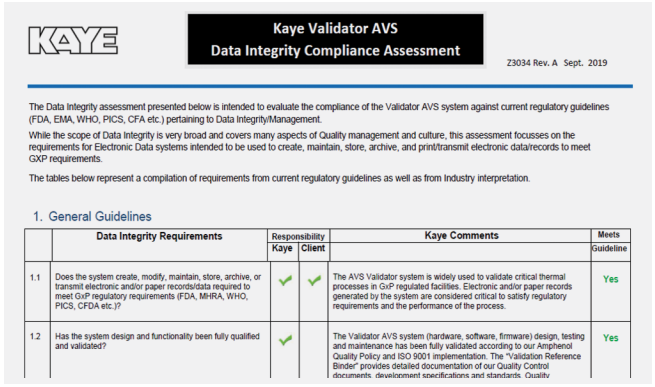
With data synchronization to a shared folder it is possible to exchange configuration and data files like your assets, setups and study files with other Kaye validation consoles. It also allows you to synchronize the user database but also merge the audit trails of several consoles enabling sorting, 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.



User Management



Policies


KAYE

Kaye Validator AVS
Data Integrity Compliance Assessment

Z3034 Rev. A Sept. 2019

The Data Integrity assessment presented below is intended to evaluate the compliance of the Validator AVS system against current regulatory guidelines (FDA, EMA, WHO, PICS, CFA etc.) pertaining to Data Integrity/Management.

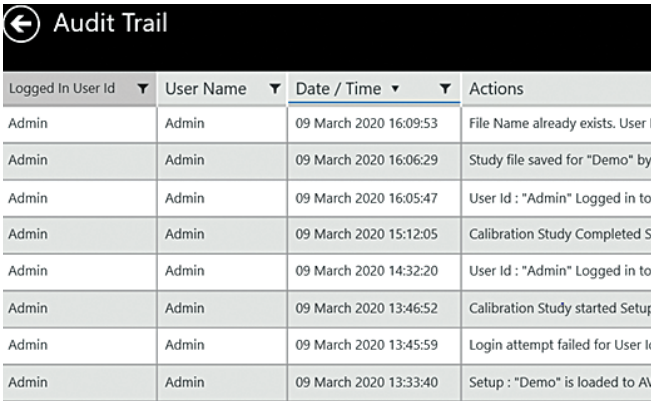
While the scope of Data Integrity is very broad and covers many aspects of Quality management and culture, this assessment focusses on the requirements for Electronic Data systems intended to be used to create, maintain, store, archive, and print/transmit electronic data/records to meet GXP requirements.

The tables below represent a compilation of requirements from current regulatory guidelines as well as from Industry interpretation.

1. General Guidelines

	Data Integrity Requirements	Responsibility		Kaye Comments	Meets Guideline
		Kaye	Client		
1.1	Does the system create, modify, maintain, store, archive, or transmit electronic and/or paper records/data required to meet GxP regulatory requirements (FDA, MHRA, WHO, PICS, CFDA etc.)?	✓	✓	The AVS Validator system is widely used to validate critical thermal processes in GxP regulated facilities. Electronic and/or paper records generated by the system are considered critical to satisfy regulatory requirements and the performance of the process.	Yes
1.2	Has the system design and functionality been fully qualified and validated?	✓		The Validator AVS system (hardware, software, firmware) design, testing and maintenance has been fully validated according to our Amphenol Quality Policy and ISO 9001 implementation. The "Validation Reference Binder" provides detailed documentation of our Quality Control documents, development specifications and standards. Quality	Yes

Data Integrity Compliance



Audit Trail Report

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 -196°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 AVS, the IRTD-400 eliminates the potential for human error, assuring accurate and traceable measurements.

FAST / ACCURATE REFERENCES

Kaye offers a complete range of baths and dryblocks to cover your sensor calibrations / verifications from -90°C to 420°C. The dry blocks are designed to offer fast heat up and cool down times, along with unmatched stability and accuracy. Additional features such as capacity to hold 48 TCs as well as specially designed TC holders, and inserts ensure maximum uniformity and minimize errors from stem conduction.

This coupled with the Automatic Calibration software utility ensures unparalleled accuracy and repeatability while minimizing random errors.

IRTD-400 (-196°C to 360°C) temperature standard

LTR-150 (-30°C to 150°C)
up to 48 Thermocouples

LTR-90 (-90°C to 150°C)
up to 15 Thermocouples

HTR-420 (30°C to 420°C)
up to 48 Thermocouples

CTR-80 (-80°C to 30°C)

Accessories

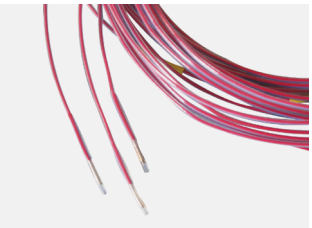
Kaye offers a wide range of accessories to support your validation needs. From ultra-premium thermocouple sensors to feedthrus, pressure transducers and much more, our goal is provide you will all the accessories, tools, documentation and services to simplify your efforts.

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

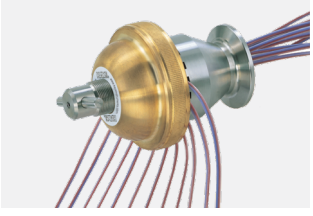
- Thermocouples for autoclaves
- Thermocouples for dry heat tunnels
- Thermocouples: stainless steel
- Thermocouples with stainless steel tip

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.



FEEDTHRU 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.



FEEDTHRU KIT

Ideal set for qualifying an autoclave with ex. one 1.5" TRI-CLAMP validation port but there is need for more than 18 Thermocouples and / or connections of a pressure transducer.

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.

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

Visit our website:
www.kayeinstruments.com

Kaye representative contact:
www.kayeinstruments.com/en/contact

Request a demo:
www.kayeinstruments.com/en/demo

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