KAYE

Validator® Accessories

Kaye Product Line

Amphenol

Advanced Sensors

Dear valued customer,

Type T thermocouples are most accurate in the temperature range of -200 to 400°C, providing more accurate, repeatable results in the validation environment.

Calibrate sensors before your validation studies. This will eliminate any hot junction conformity errors. Then verify them after the study is complete.

Use one continuous wire length — no connectors or extension wires. Use the highest quality wire available — high purity wire is less prone to errors from temperature gradients that exist in the validation test (but are not present in sensor calibration).

Use stranded wire rather than solid wire to minimize material degradation errors due to cold working.

Volker Luebcke
Global Service Leader

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.

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Thermocouples Overview

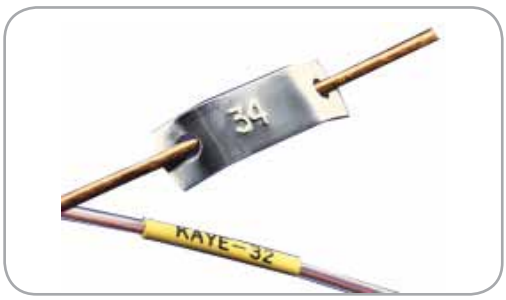
Quality Assurance

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.

Which Costs More: Material or Time?

While quality wire does cost more, the cost of unnecessarily repeating a single validation study far exceeds the price of the wire (time, lost productivity, equipment downtime). Without understanding the effects of cold working, you could lose a validation study and not know why. And the risk of it happening again is still present. This could explain why many companies discard their wire after only a few studies. In any case, specifying high-purity wire and handling your sensors more carefully is always a good practice, and will result in more accurate process measurement.

Often while using more than 10 thermocouples in a qualification run, it is more than helpful if the thermocouples are labeled close to the tip and at the SIM end. Kaye is offering kits to label the



Thermocouples yourself or you can also order already pre-labeled thermocouples from Kaye.

We also offer the pre-wiring to new SIMs – when you order new TC and SIMs at the same time.

High-Accuracy Type “T” Thermocouple Wire

As an integral component of high-accuracy measurement systems, thermocouple wire is subject to severe conditions and, often, not-so-delicate handling. Repeated bending, or cold working, of a thermocouple can generate stress and distortion of the material crystalline structure, resulting in significant potential for measurement error. Kaye thermocouple wire is a multi-strand construction using wire of the highest purity and uniformity available, thus minimizing, if not eliminating, measurement error resulting from cold working and raw material inconsistencies. Other commercially available copper/contantan thermocouple wires carry a standard grade accuracy rating of 0.75% at 121° C. For critical process validation applications, Kaye Ultra-Premium wire is the proven standard, delivering 0.21% accuracy (almost four times more accurate than standard wire). Kaye thermocouple wire is available in three- and seven-strand configurations with clear Teflon® insulation. The 3-strand wire is intended for applications where space is limited, or where the wire must be fed through very narrow openings. The Teflon® coated thermocouple wire is rated for continuous use at 200° C with a peak rating of 260° C, while our Kapton® insulated wire will withstand service to 350° C.

Teflon® Tips Extend Thermocouple Life

Encapsulating the sensor tip with dual shrink Teflon® tubing will extend the life of your thermocouple. A sealed tip guards against moisture being pulled along the wire, thus minimizing oxidation and doubling the life of your probe (saving you the cost and time of buying and calibrating replacement sensors). Kaye thermocouple wire is a multi-strand construction using wire of the highest purity and uniformity available, thus minimizing, if not eliminating, measurement error resulting from cold working and raw material inconsistencies.

Thermocouples for Autoclaves

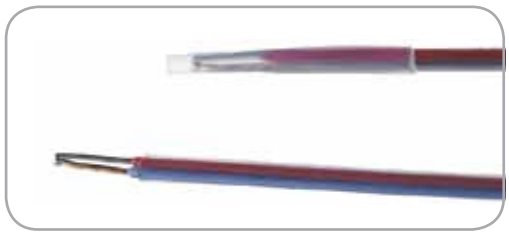
Ultra-Premium Type T Teflon® Insulated Thermocouples

Each Teflon® Thermocouple is leakage vacuum tested and verified for accuracy @ 40°C and 121°C.

For critical process validation applications, Kaye Ultra-Premium wire is the proven standard, delivering 0.21% accuracy (almost four times more accurate than standard wire).

The Teflon® coated thermocouple wire is rated for continuous use from -100°C up to 200° C with a peak rating of 260° C. Encapsulating the sensor tip with dual shrink Teflon® tubing will extend the life of this thermocouple.

A sealed tip guards against moisture being pulled into the wire, thus minimizing oxidation and doubling the life of your probe. Available as 3- and 7-stranded thermocouple.



Typical applications

- Freezers
- Incubators, Chambers
- Autoclaves, Raining autoclaves
- SIP

Technical Details

- Thermocouple tips with 1.8 mm or 3 mm diameter
- Temperature range from -100°C to 200°C
- Accuracy of 0.1°C @ 40°C and 0.25°C @ 121°C
- Ideal for wet applications
- Continuous use up to 200°C with a short time peak of 250°C
- Available as 3- or 7-stranded wire
- Available also with Labels
- Standard length of 6-8-10-12 m (EMEA)
- Standard length of 30-35-40-45-50 feet (US)

Standard Part Numbers

USA/Asia

7ST 1WY-20	Teflon Probe, 7-stranded, 1'' Tip, 20 feet
7ST 1WY-25	Teflon Probe, 7-stranded, 1'' Tip, 25 feet
7ST 1WY-30	Teflon Probe, 7-stranded, 1'' Tip, 30 feet
7ST 1WY-40	Teflon Probe, 7-stranded, 1'' Tip, 40 feet
3ST 1WY-20	Teflon Probe, 3-stranded, 1'' Tip, 20 feet
3ST 1WY-30	Teflon Probe, 3-stranded, 1'' Tip, 30 feet
3ST 1WY-35	Teflon Probe, 3-stranded, 1'' Tip, 35 feet
3ST 1WY-40	Teflon Probe, 3-stranded, 1'' Tip, 40 feet

Europe

7ST1W-20N	Teflon Probe, 7-stranded, 1'' Tip, 6 m
7ST1W-27N	Teflon Probe, 7-stranded, 1'' Tip, 8 m
7ST1W-33N	Teflon Probe, 7-stranded, 1'' Tip, 10 m
7ST1W-40N	Teflon Probe, 7-stranded, 1'' Tip, 12 m
3ST1W-20N	Teflon Probe, 3-stranded, 1'' Tip, 6 m
3ST1W-27N	Teflon Probe, 3-stranded, 1'' Tip, 8 m
3ST1W-33N	Teflon Probe, 3-stranded, 1'' Tip, 10 m
3ST1W-40N	Teflon Probe, 3-stranded, 1'' Tip, 12 m

Thermocouples for Dry Heat Tunnels

Ultra-Premium Type T Kapton® Insulated Thermocouples

For critical process validation applications, Kaye Ultra-Premium wire is the proven standard, delivering 0.21% accuracy (almost four times more accurate than standard wire). The Kapton® insulated thermocouple wire is rated for continuous use up to 260°C for 3 months and max. temperature of 350°C for 6 days.

Typical applications

- Dry heat tunnels
- Incubators
- Ovens

Technical Details

- Stainless Steel tips - 3 mm diameter and Kapton® wire
- Accuracy of 1.2°C @ 300°C
- Max. Temperature 350°C for 6 days
- 300°C for 3 months
- Continuous use up to 260°C for 3 months
- NO wet applications
- Available only as 7-stranded wire
- Available also with metal Labels
- Standard length of 6-8-10-12 m (EMEA)
- Standard length of 30-35-40-45-50 feet (US)

Standard Part Numbers

USA/Asia		Europe	
KW-20	Kapton Probe, 7 stranded, 20 feet	KW-20	Kapton Probe, 7 stranded, 6 m
KW-25	Kapton Probe, 7 stranded, 25 feet	KW-27	Kapton Probe, 7 stranded, 8 m
KW-30	Kapton Probe, 7 stranded, 30 feet	KW-33	Kapton Probe, 7 stranded, 10 m
KW-40	Kapton Probe, 7 stranded, 40 feet	KW-40	Kapton Probe, 7 stranded, 12 m
KW-60	Kapton Probe, 7 stranded, 60 feet	KW-47	Kapton Probe, 7 stranded, 14 m

Thermocouples: Stainless Steel

Stainless Steel Mineral Insulated Thermocouple Type T:

Type T Thermocouple – Class A with temperature range of -200°C to 400°C with a 1 mm diameter for the stainless steel and a Silicon connection cable which allows maximum 100°C. The connection point of this thermocouple cannot be in the autoclave – only the stainless steel sensor is allowed in the autoclave.

Typical Applications:

- Freeze Dryer, Freezers, Liquid Nitrogen tanks
- Incubators, Autoclaves, Raining autoclaves
- Type T - Class 1 Quality

Technical Details

- Thermocouples with 1 mm diameter
- Temperature range from -200°C to 400°C
- Type T - Class 1 Quality
- Accuracy of ±0.5 between –40 °C and 125 °C
- ±0.004×T between 125 °C and 350C

Standard Part Numbers

Global Part No

KG-1SST-6-2-8M

Stainless Steel mineral insulated Thermocouple Type T

6m sensor / 2m cable / 8 m total length

1mm diameter / -200°C to 400°C / Class 1

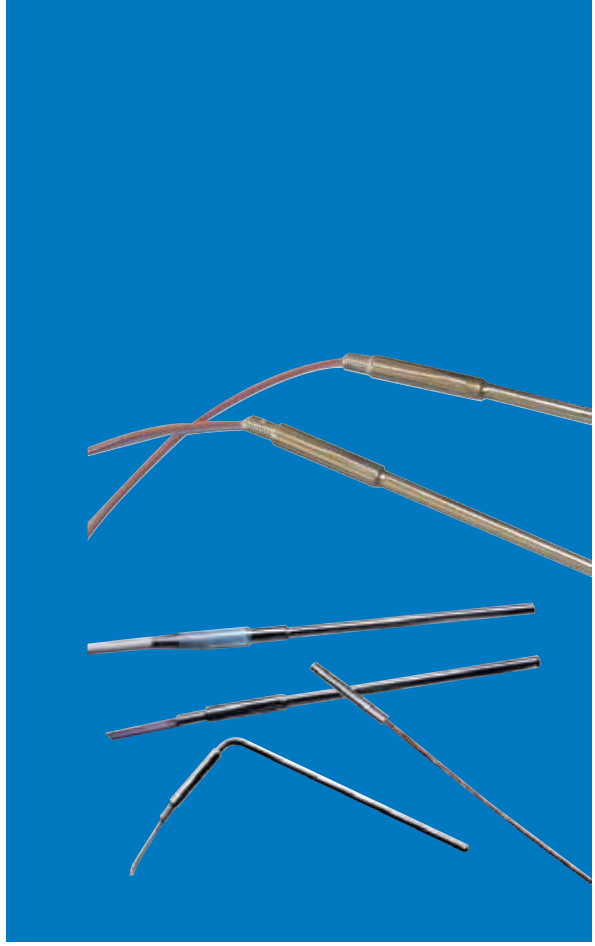
KG-1SST-6-6-12M

Stainless Steel mineral insulated Thermocouple Type T

6m sensor / 6m cable / 12 m total length

1mm diameter / -200°C to 400°C / Class 1

Thermocouples with Stainless Steel Tip



Type T - Stainless Steel Thermocouple Tips

The stainless steel probes are available in straight or right angle configurations with rounded or pointed tips, and are available in any length with diameters of 3.2 or 4.8 mm. Kaye probes are constructed of one continuous length of our Ultra-Premium wire, providing superior accuracy and eliminating errors inherent in other probes which have a wire transition between the stainless steel stem and the thermocouple extension.

Technical Details

- Thermocouple tips with 3.2 or 4.8 mm diameter
- Temperature range from -100°C to 200°C
- Accuracy of 0.1°C @ 40°C and 0.25°C @ 121°C
- Straight or right angle stainless steel sensor
- Available as 3-stranded or 7-stranded wire

STAINLESS STEEL TEFLON PROBE

Part Number Matrix 7ST-20-L-S-4-P-W- Y

- Wire Length in feet
- Y for labels
N for no labels
- C for connector (EO739)
W for with out connector
V for mini conn. (E0749)
- P for pointed tip
F for flat tip
- Tip length in inches
- S for straight probe
B for 90 degree bend
- S for 1/8 inch dia. SS probe tube
- L for 3/16 inch dia. SS probe tube
- 7ST for Ultra Premium
7 Stranded K0255
- P7ST for Premium
7 Stranded K0254
- 3ST for Ultra Premium
3 Stranded (K0258)

Thermocouples Accessories

Thermocouple Spools – To Make Thermocouples Yourself

Each spool of wire includes a Certificate of Conformance — your guarantee that it meets the accuracy specifications listed above. The Teflon® coated thermocouple wire is rated for continuous use from -100°C up to 200° C with a peak rating of 260° C. Available in 3 and 7 stranded wire.

Global Part No:	
7-Stranded Thermocouple Wire Spool:	K0255
3-Stranded Thermocouple Wire Spool:	K0258

Thermocouple Labels

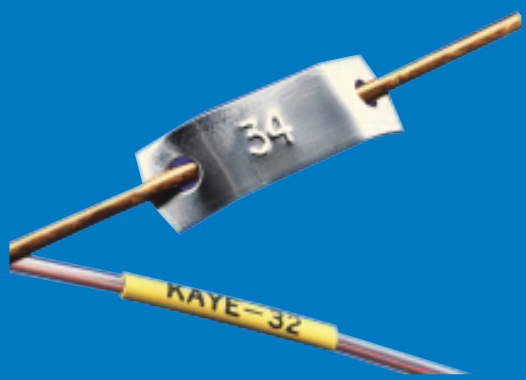
These labels make it easy to identify each thermocouple and document the qualification of chambers easily. You just add them on the Teflon®-Thermocouple and use a heat gun to shrink them onto the thermocouple cable. Set of 36 TCs - 2 numbers each.

Global Part No:	
Labels for Teflon Thermocouple Probes:	V2007
Labels for Kapton Thermocouple Probes:	M2105

Thermocouple Kit

Extend the life of yourself welded thermocouples by encapsulating the tip in a sealed PTFE sleeve. The kit is available for 3- and 7-strand Type T thermocouple wire. Each kit provides material to make between 45 and 60 sensor tips.

Global Part No:	
Thermocouple Kit for 7-Stranded Teflon Probes:	V1770
Thermocouple Kit for 3-Stranded Teflon Probes:	V1775



Feedthru

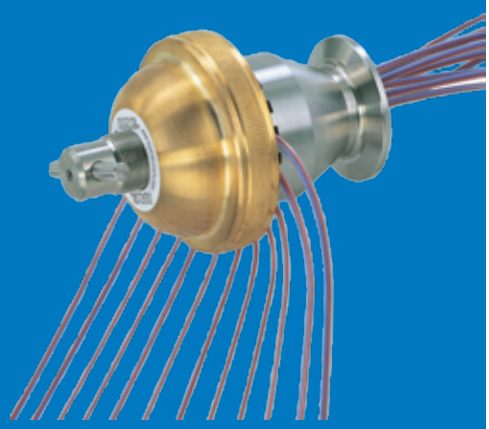
Feedthru for Autoclave Applications

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.

Stainless steel thermocouple feedthru:

- Allows up to 18 thermocouples to be introduced into the validated chamber.
- Standard 1.5” TRI-CLAMP® process connection
- Fitted with safety release mechanism
- TÜV approved for up to 5 bar steam pressure
- Delivered with special gasket for great seal
- Improved design for use with autoclave
- Temperature up to 140°C

Part No USA/Asia:	K0440
Part No Europe:	KG-150

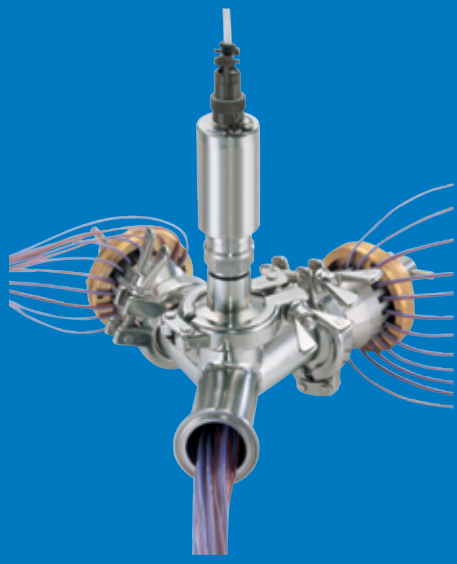


Feedthru-Kit for TCs and Pressure Sensor

This Feedthru-KIT is an ideal set if you have to qualify an autoclave which has for example only one 1.5” TRI-CLAMP® validation port but you need to use more than 18 thermocouples or you want to connect a pressure sensor as well to the autoclave. Simple installation is all you need to perform the work.

Feedthru kit contains the following parts:

- One 1 ½” Kaye Feedthru including gasket seals
- Stainless Steel Y-piece with 4 x 1.5” TRI-CLAMP® process connection
- TÜV approved for up to 5 bar pressure
- Delivered with 4 x TRI-CLAMPs®
- Delivered with 4 high temperature gaskets for autoclave
- Include as well 2 stainless steel lids for 1.5” TRI-CLAMP®
- Kit is delivered in a transport case



Part No USA/Asia:	V2845
Part No Europe:	KG-144

Y-Piece for Autoclave Applications

Ideal part if you have to qualify an autoclave which has only one 1.5” TRI-CLAMP® validation port but you need to use more than 1 feedthru or you want to connect a pressure transducer as well to the autoclave.

STAINLESS STEEL Adapter Y-Piece:

- Allows connecting of 2 Feedthrus and Pressure Transducer
- 4 x Standard 1.5” TRI-CLAMP® process connection
- Pressure tested up to 8 bar
- Leakage tested helium-vacuum-leak-detector (< 10-7 mbarl/s)

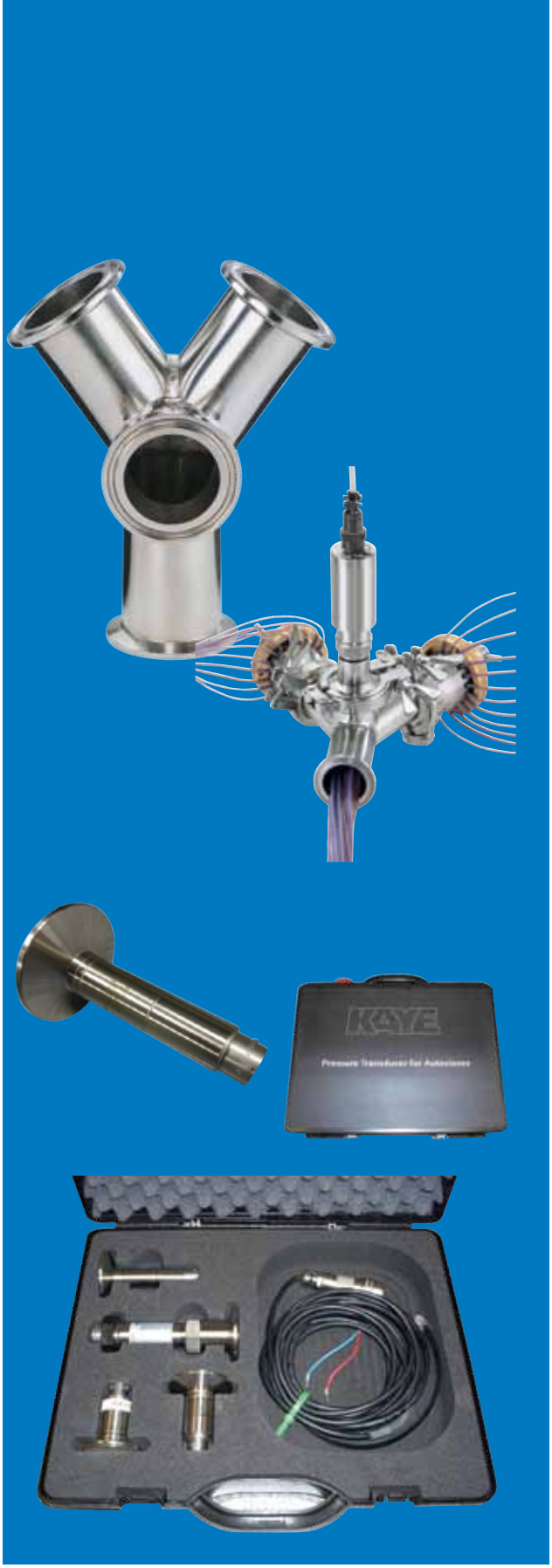
Part No USA/Asia:	K0442
Part No Europe:	KG-148

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® 2000 – no power supply required.

Kaye Autoclave Pressure Transducer

- Media temperature -20°C to 140°C
- Accuracy of 10 mbar @ 121°C
- Pressure range 0 to 4 bar absolute
- Including cable to connect directly to Kaye Validator®
- Delivered in a protective carry case
- No power supply required
- Pressure value can be handled directly by the Validator®
- 1.5 inch TRI-CLAMP® Connector to install directly to the autoclave port
- Improved design for use with autoclave (T-compensated)
- New units delivered with certificate @ 23°C and 121°C



Global Part No: KG-075

Validator® Shipping Case

Protect your Validator® and store it safely when not being used

Shipping Case – Why Should You Own It

- Robust, secure and practical, shock protection during transport
- Can be used as a trolley for easy transportation
- Provides safety during shipments and internal transportation
- Safe shipment and transport for annual service
- Specific storage inserts for all accessories/documentation
- Protects against moisture, dust and pollution – waterproof
- Given the best storage when system not in use
- Can be locked to prevent theft and unauthorized usage

Technical Details

- 60 cm x 40 cm x 40 cm
- 10 kg without Validator®
- 2 wheels to use as a trolley

Part No USA/Asia:	M0275-1
Part No Europe:	KG-CASE-VAL

USB Upgrade for Kaye Validator®

Some older Validators are still using a floppy drive to store data or an RS-232 serial Port for communication with a Laptop. Floppies are basically not available anymore and new laptops are delivered with USB ports only.

So an upgrade of older Validators is required to stay up to date with current computer and storage media

- Add USB communication to your Validator® 2000
- Add USB drive so data is stored in the future not on floppy any more but on USB stick – this will make data store more secure, easy and much better to be transferred to the PC
- Upgrade will also allow using current software with the Validator® which supports WIN7 and 64 bit

Global Part No:

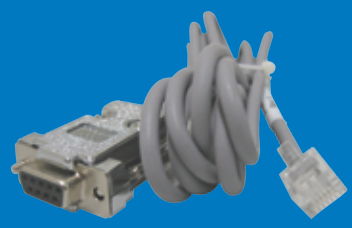
V2080 USB Stick Upgrade

V2082 USB Com Upgrade

Cables for Kaye Validator®

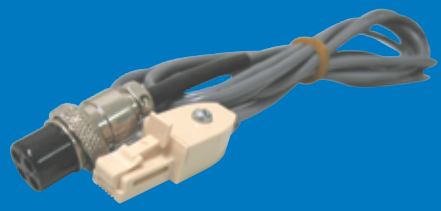
- Oven Cable - about 1.5 meter long
- Connects the Validator® with Kaye LTR / HTR / CTR baths

Global Part No: W1885-1



- IRTD Cable - about 1.5 meter long
- Connects the Validator® with the IRTD-400

Global Part No: M2810-1



- USB Cable - about 1.5 meter long
- Connects the Validator® with PC/Laptop

Global Part No: 238-098

- RS232 Cable - about 1.5 meter long
- Connects the Validator® with PC/Laptop

Global Part No: W1890-1

- Cable for autoclave pressure transducer
- About 5 meters long
- Connects the Validator® SIM with the pressure transducer and powers the pressure transducer from the Validator® 2000

Global Part No: KG-075 Cable-G

Kaye Validator® E-Training

Kaye Validator® E-Training, Version 3.x

The Kaye Validator® is a powerful instrument for execution and documenting thermal validation studies. Our self-paced e-learning class is designed to provide a thorough understanding of the system's capabilities and operation from the comfort of your own office. The course is broken into a series of 9 discrete modules, each covering a single aspect of executing a thermal validation study using the Kaye Validator®.

The training program simulates the Kaye Validator® software step-by-step and lets you try the more complex procedures on your own. Subject matter is presented using detailed audio and product simulations, and hands-on exercises reinforce key elements. Assessments at the end of each module confirm subject mastery, and certificate is provided upon Successful course completion.

The program is an easy, cost-effective way of ensuring that every user meets company and regulatory training requirements.

Topics covered:

- Interface connections
- Security
- Setup/programming
- Running calibrations and calibration verifications
- Running qualification studies
- Generating reports
- Using the Report Wizard
- Running in Standalone mode

Upon order confirmation, you will receive an e-mail with a unique user ID and password that will provide access to the online training program.

User ID and password combinations are valid through successful completion of the final module, but do expire after ninety days. Once all module assessments are passed, a certificate of completion will be forwarded to the registrant.

On-site Training

If you are using Kaye equipment and would like training at your facility, we can schedule a visit to suit you.

Our technical instructors can assist you with all your training needs in the format, location and pace that works best for you and your team. Training courses are held at a number of convenient regional training centers. Our courses range from introductory level to in-depth product classes with practical hands-on exercises. All courseware is coordinated with the most recent product updates and features. On request, we offer product specific on-site training courses to meet your particular needs.

IQ/OQ Protocol

The Installation Qualification/Operational Qualification Protocol defines a set of procedures to ensure that the Kaye Validator system is properly installed and operated according to Kaye 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
- Standard Operating Procedures document
- Set-up programs

Global Part Number: X6005

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