







# KAYE

**Validation / Monitoring Solutions to Meet your Needs**



# Solutions for Pharmaceutical & Biotechnology Industries




| Process Validation  |   |   |
|---|---|---|
| Product:  | Applications:   | Features:   |
| <p>Kaye Validator® AVS</p>   | <p>Wired Thermal Validation</p> <ul style="list-style-type: none"> <li>• Steam Sterilizers / Autoclaves</li> <li>• Dry Heat Tunnels / Ovens</li> <li>• Freeze Dryers</li> <li>• Steam in Place /SIP systems</li> <li>• CTU Controlled Temp Units</li> <li>• Freezers, refrigerators, incubators</li> <li>• Warehouse</li> </ul> | <ul style="list-style-type: none"> <li>• Kaye Validator AVS Console dedicated for Validation</li> <li>• OS and hardware controlled and validated by Kaye</li> <li>• Common Software tools for Kaye hardware</li> <li>• Backwards compatible to existing Kaye products</li> <li>• Eliminates IT control</li> <li>• Intuitive metro-style touch screen interface</li> <li>• Simplified Validation (GAMP5)</li> <li>• Asset Centric Data Management concept</li> </ul> |
| <p>Kaye Validator® 2000</p>  | <p>Wired Thermal Validation</p> <ul style="list-style-type: none"> <li>• Steam Sterilizers / Autoclaves</li> <li>• Dry Heat Tunnels / Ovens</li> <li>• Freeze Dryers</li> <li>• Steam in Place /SIP systems</li> <li>• CTU Controlled Temp Units</li> <li>• Freezers, refrigerators, incubators</li> <li>• Warehouse</li> </ul> | <ul style="list-style-type: none"> <li>• Industry standard for wired thermal validation</li> <li>• Enables compliance to cGMP and 21 CFR part 11</li> <li>• Create complaint reports easily and fast</li> <li>• Network capability for passwords and audit trails</li> <li>• USB Data Storage &amp; Communication</li> <li>• Common reporting tool for all validation products</li> </ul>   |

| Wireless Process Validation   |   |  |
|---|---|--|
| Product:  | Application:  | Features:  |
| <p>Kaye ValProbe® Family</p>                  | <p>In situ wireless data loggers</p> <ul style="list-style-type: none"> <li>• Steam Sterilizers / Autoclaves</li> <li>• Dry Heat Tunnels / Ovens</li> <li>• Freeze Dryers</li> <li>• Freezers, refrigerators, incubators</li> <li>• Warehouse</li> <li>• Transportation, Logistics</li> </ul> | <ul style="list-style-type: none"> <li>• Delivers unrivaled measurement accuracy over a wide operating range</li> <li>• Easily defined cycle-based data collection, calculation, and reporting from up to 150 sensors</li> <li>• Designed for easy on-site calibration</li> </ul>  |
| <p>Combined Temperature/Pressure Logger</p>  | <ul style="list-style-type: none"> <li>• Steam Sterilizer Validation</li> <li>• Hospital Validation and Routine Control</li> <li>• Small scale sterilization in dental offices</li> <li>• Parametric release applications</li> </ul>  | <ul style="list-style-type: none"> <li>• 10,000 data sample memory</li> <li>• Cost effective field-replaceable battery</li> <li>• Operator programmable sample rates from 1 sec to 12 hours</li> <li>• Configurable start, change and stop events</li> <li>• Enables compliance with ISO-17665, EN285 and HTM-2010</li> </ul>  |
| <p>Cryo Logger</p>                           | <ul style="list-style-type: none"> <li>• Cryogenic Vessels</li> <li>• Freeze Dryer</li> <li>• Freezers</li> <li>• Incubators</li> <li>• Warehouses</li> <li>• Sterilizers</li> </ul>  | <ul style="list-style-type: none"> <li>• Temperature Range for complete logger: -85°C to 140°C</li> <li>• Field replaceable 3.6 V lithium thionyl chloride battery</li> <li>• Battery life performance: 1600 h at 1 sec at 20°C, 300 h at 10 sec at -85°C</li> </ul>   |
| <p>Freeze Dryer Logger</p>                   | <ul style="list-style-type: none"> <li>• Cryogenic Vessels</li> <li>• Freeze Dryer</li> <li>• Freezers</li> <li>• Incubators</li> <li>• Warehouses</li> <li>• Sterilizers</li> <li>• Surface Measurement</li> </ul>   | <ul style="list-style-type: none"> <li>• Surface temperature logger design provides enhanced and precision wireless measurement capability ideal for freeze dryer shelf temperature measurements.</li> <li>• Unique integrated design with embedded RTD technology</li> <li>• Wireless sensing design that maximizes thermal response time and performance</li> <li>• Self-adhering thermal pad insures continuous thermal conductivity during vacuum cycles for ultimate surface measurement performance</li> <li>• Temperature range for complete logger: -85°C to +140°C</li> </ul> |

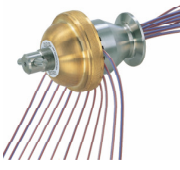


## Real-Time Wireless Process Validation

| Product:  | Applications:  | Features:  |
|---|--|--|
| <p>Kaye RF ValProbe® II</p>  <p><b>NEW</b></p> | <p>The Kaye RF ValProbe II integrates breakthrough RFMesh technology with enhanced technology thermal validation in situ loggers.</p> <p>The Kaye RF ValProbe II loggers operating range of -40°C to +60°C and temperature sensor range of -200°C to +200°C make them ideal for real-time RF validation and monitoring of environmental chambers, warehouses, freezers, refrigerators and steam-in-place (SIP) applications.</p> | <ul style="list-style-type: none"> <li>RF Mesh Networking technology provides reliable real time process data. Uses global 2.4 GHz RF frequencies</li> <li>Provides 100% data redundancy in both remote logger and base station in addition highly reliable RF network</li> <li>Additional options for redundancy data retrieval and backup using micro SD card and USB</li> <li>Industrial design with integrated LCD Display</li> <li>Emergency Battery backup for base station (30 min) for uninterrupted operation using 3.7V AA size Lithium rechargeable batteries</li> <li>Dual powered, logger runs on AC Power and/or Battery. Battery life greater than 1 year in typical use, using Standard 3.6V AA Primary Lithium batteries.</li> <li>Report tool can process and create merged reports from RF ValProbe, ValProbe or Validator products.</li> </ul> |
| <p>Steam in Place</p>                          | <p>Real-Time Wireless Datalogger for Steam in Place Application</p> <ul style="list-style-type: none"> <li>Pharmaceutical Industry</li> <li>Dairy Industry</li> <li>Beverage Industry</li> <li>Biotechnology Industry</li> </ul>   | <ul style="list-style-type: none"> <li>T/P accuracy meets Pharma sterilization requirements.</li> <li>RF Mesh Networking provides reliable real-time process validation data</li> <li>Provides 100% data redundancy in both remote logger and base station</li> <li>Greater than 1 year battery life in typical use, using Standard AA Lithium batteries.</li> <li>Easy connection to Kaye Pressure transducer</li> <li>Can be directly connected to 1.5 in triclover flange via SmartGasket®</li> <li>Standard auto calibration function</li> </ul>   |
| <p>Kaye RF ValProbe®</p>                     | <p>Real-Time Wireless Validation System for Standard Validation Application</p> <ul style="list-style-type: none"> <li>Temperature Mapping, Validation</li> <li>Warehouses, Storage Areas</li> <li>Refrigerators, Freezers, Walk-Ins</li> <li>Incubators, Chambers</li> <li>Transportation, Logistics</li> </ul>   | <ul style="list-style-type: none"> <li>Ultra-Reliable, fully redundant RF Mesh Technology</li> <li>Industry's first Validatable RF Wireless System</li> <li>Enables compliance to cGMP and 21 CFR</li> <li>Create complaint reports easily and fast</li> </ul>   |



## Temperature Calibration

| Product:  | Application:  | Features:  |
|---|---|--|
| <p>Kaye CTR, HTR &amp; LTR Series</p>  | <p>Liquid Baths &amp; Dry Wells</p> <ul style="list-style-type: none"> <li>High-temperature applications such as autoclaves, dry heat ovens and sterilizer tunnels.</li> <li>Low-temperature performance for applications including freezers, cold rooms, incubators and autoclaves.</li> </ul> | <ul style="list-style-type: none"> <li>Automatic control and fast heat up and cool down speeds up sensor calibration</li> <li>Drywells and Oil baths cover operating range of Validator and ValProbe.</li> <li>Rugged and lightweight baths and references</li> </ul>                              |
| <p>LTR-90</p>                          | <p>Kaye LTR-90 ultra-cool dry well calibrator.</p> <p>Designed for portability and ease of operation from -95°C to +140°C.</p>  | <ul style="list-style-type: none"> <li>Stirling cooler technology: reaches -80 °C in 60 min; -95 °C in 80 min</li> <li>Temperature stability of ±0.015 °C &amp; Axial Uniformity 0.05°C Full Range</li> <li>Ergonomics/industrial design with two-handle carry. Weight: 16 kg (35 lbs.)</li> </ul> |
| <p>IRTD Temperature Standard</p>       | <p>The intelligent resistant temperature device (IRTD) is a secondary standard. The self-contained IRTD allows you to cut system error in half while eliminating the cost and effort of calibrating supporting equipment.</p>   | <ul style="list-style-type: none"> <li>Temperature range -195 to 420°C</li> <li>Accuracy over range ±0.025°C</li> <li>Resolution 0.001 °C</li> <li>DAkKS Certified Calibration, Traceable to NIST</li> </ul>   |

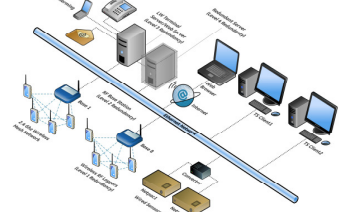

## Validation Accessories

| Product:   | Applications:   | Features:   |
|--|---|---|
| Kaye Feedthru<br>                       | <ul style="list-style-type: none"> <li>• Feedthru's for autoclaves and freeze dryers</li> <li>• Feedthru triclover kits including clamps and gaskets</li> </ul>   | <ul style="list-style-type: none"> <li>• Feedthru accommodates from 1 to 18 thermocouples of any diameter</li> <li>• TÜV certified for pressure vessels from -1 bar /+5 bar, and -60°C / + 160°C</li> <li>• Standard 1.5" tri-clamp connections</li> <li>• Easily installed with no tools required</li> </ul> |
| Kaye Validator® Pressure Transducer<br> | <ul style="list-style-type: none"> <li>• Designed for the harsh environment applications such as steam sterilizers and SIP systems</li> <li>• High performance pressure transducer, specified full temperature range of autoclaves</li> </ul> | <ul style="list-style-type: none"> <li>• Directly connectable to 1.5 triclover flange</li> <li>• Full ISO-17025 traceable calibration over pressure and temperature range</li> <li>• 0 bar to 4 bar (59psia) absolute</li> <li>• +110°C to 140°C</li> </ul>   |
| Highest Quality Thermocouple Wire<br>   | Thermocouple wire is manufactured with the highest purity and uniformity available to the industry.   | <ul style="list-style-type: none"> <li>• Available in 3 or 7 strand constructions</li> <li>• Available uncut in spools or cut to length with Teflon tips</li> </ul>   |

## Calibration / Service Contracts / Rental / IQ-OQ execution

| Product:   | Application:  | Features:  |
|--|---|--|
| Equipment Rental<br> | We offer a comprehensive range of products suitable for your short term Temperature / Validation needs. <ul style="list-style-type: none"> <li>• Validator2000</li> <li>• Calibration Bath/ Dry Wells</li> <li>• DAkkS Temperature Standard</li> <li>• ValProbe Loggers</li> <li>• RF ValProbe – wireless system</li> <li>• Accessories like Feedthru or Pressure Transducer</li> </ul> | Rent a complete validation system or just the equipment you need to extend your existing setup.: <ul style="list-style-type: none"> <li>• Pay as you need it and keep capital spending low</li> <li>• Short- and Long-term rental for unexpected projects or changes in project requirements</li> <li>• Rentals allow you to be fully operational with up-to-date equipment when unforeseen challenges arise</li> <li>• Easy way to test equipment before purchasing</li> <li>• Factory guarantee with technical support—our specialists assist you with fast, competent service right over the phone</li> </ul> |
| Services<br>        | <ul style="list-style-type: none"> <li>• IQ/OQ Execution</li> <li>• Rental &amp; Leasing</li> <li>• Calibration</li> <li>• EMA's (Gold / Silver Contracts)</li> <li>• Validation Training</li> </ul>  | <ul style="list-style-type: none"> <li>• World Class Calibration Labs</li> <li>• Include NIST or DAkkS &amp; UKAS certified for Temperature, Humidity and Pressure</li> <li>• Onsite calibration and IQ/OQ execution</li> <li>• Peace of mind through Extended Maintenance Agreements</li> <li>• Worldwide rental fleet fulfills short term equipment needs</li> </ul>   |

## Facility / Stability Monitoring

| Product:  | Applications:  | Features:  |
|---|--|--|
| <p>Kaye LabWatch™ Pro</p>  | <p>Centralized monitoring, alarming and reporting system</p> <ul style="list-style-type: none"> <li>• Stability Chambers</li> <li>• Freezers</li> <li>• Refrigerators</li> <li>• Incubators</li> <li>• Cryogenic Freezers</li> <li>• LN2 tanks</li> <li>• Ovens</li> </ul>   | <ul style="list-style-type: none"> <li>• Wireless Sensor Capability utilizing RF ValProbe</li> <li>• Interface to Pre-Existing/3rd party Sensors</li> <li>• Enables compliance with FDA regulation 21 CFR Part 11</li> <li>• Robust and Scalable System Architecture</li> <li>• Provides a complete history of alarms, notification and data in one central location, automatically</li> <li>• Regulatory compliant data reporting</li> </ul>  |
| <p>Kaye LabWatch™ LT</p>  | <p>Where We Monitor:</p> <ul style="list-style-type: none"> <li>• Warehouses</li> <li>• Repositories</li> <li>• Clean Rooms</li> <li>• Blood Banks</li> <li>• Tissue Banks</li> <li>• Pharmacies</li> <li>• Cold Storage</li> <li>• Animal Rooms</li> <li>• Laboratories</li> </ul> <p>What We Monitor:</p> <ul style="list-style-type: none"> <li>• Stability Chambers</li> <li>• Freezers</li> <li>• Refrigerators</li> <li>• Incubators</li> <li>• Cryogenic Freezers</li> <li>• LN2 Tanks</li> <li>• Ovens</li> <li>• Baths</li> </ul> | <ul style="list-style-type: none"> <li>• Operates in compliance with the FDA regulation 21 and CFR Part 11.</li> <li>• Audit trail of alarms and actions taken by the system and the people who log onto the system in one central location automatically.</li> <li>• Reliable alarm detection protects your time by avoiding nuisance alarms and guards your product investment.</li> <li>• Unlimited alarm notification to handle specific alarm conditions with a variety of notification methods via phone and e-mail.</li> <li>• Retrieve data easily for viewing, reporting, analysis, and regulatory inspection.</li> <li>• Secure data storage via encryption of files to prevent tampering.</li> <li>• Runs on reliable, up-to-date Windows platform software.</li> </ul> |