

GE Sensing

The Kaye Validator is a standalone thermal validation system that simplifies the entire validation process by reducing setup time, minimizing sensor handling, and presenting critical study data in easily customized report formats. Version 3.0 now incorporates the latest technology for faster data collection, improved data management and more flexible reporting and analysis, providing significant time saving over previous releases.

This advanced system is specifically designed to conform with 21 CFR Part 11 and to meet international and European norms for validation of pharmaceutical, biotechnology and medical device (EN285, EN554) manufacturing plants.

Features

- Intuitive study setup and extensive process calculations simplify the validation process
- Improved data analysis, including ability to graph and report unlimited cycles and up to 25 groups
- Centralized network management of all passwords and audit trails
- Ability to merge data files from multiple Kaye Validator and ValProbe® studies
- Sensor input modules minimize sensor handling and calibration, including 4/20 mA inputs
- Fully automated sensor calibration
- Operates standalone or with PC
- Enables compliance with FDA 21 CFR Part 11 guidelines
- Total system accuracy, following Guidelines for Uncertainty Measurement, of 0.17°C (k=2)

Kaye Validator®

Thermal Validation System

Kaye Instruments has joined other GE high-technology sensing businesses under a new name—GE Industrial, Sensing.



GE Sensing

IDs and passwords are required to start and stop a process, check configuration, or calibrate sensors.

Displays online data and calculations, setup parameters and sensor offsets.

Internal memory protects test results in progress, ensuring backup if floppy is full or printer fails.

Sensors are connected via three Sensor Input Modules which accommodate up to 12 sensors each, including 4/20 mA inputs. Built-in memory retains calibration offsets.

USB port allows direct connection between PC and Validator for downloading studies.



Kaye Validator back

Any action affecting user data can be permanently captured in a comprehensive audit trail, which can be automatically stored at a network location. System administrators can now have fully automated management of passwords, audit trails and data files across all validation groups.

Qualification Reports present raw process data for individual sensors, statistical calculations selected during study setup, and accumulated lethality for individual sensors.

Summary reports present study setup details and post-study user comments, along with group interval and lethality calculations, as well as data for each group and cycle.

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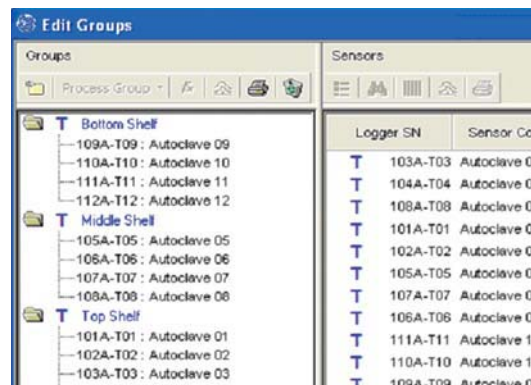
The screenshot shows a 'Qualification Summary Report' with the following structure:

- Heating Data:** A table with columns for Heating (Min, Max, Avg, ALev) and Evacuation (Min, Max, Avg, ALev) for each of three cycles (1, 2, 3).
- Evacuation Data:** A table with columns for Evacuation (Min, Max, Avg, ALev) and Cooling (Min, Max, Avg, ALev) for each of three cycles.
- Cooling Data:** A table with columns for Cooling (Min, Max, Avg, ALev) for each of three cycles.
- Summary Statistics:** A table with columns for Heating, Evacuation, and Cooling, each with sub-columns for Min, Max, Avg, and ALev.

Summary report

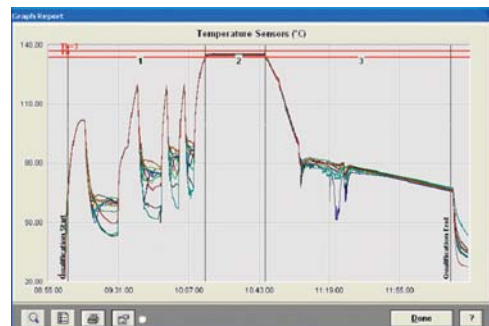
Data files can be merged from multiple Validator and ValProbe studies.

Users can add unlimited cycles, separating qualification data into specific process phases, and up to 25 groups with their own calculations and graphs during reporting, eliminating the need to download to Excel®.



Groups screen

A new powerful graphing utility greatly simplifies process analysis and reporting. More inputs, colors and data limit lines have also been added.



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