Kaye Validator®

Thermal Validation System

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 3.5 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

- Operates standalone or with PC

- Fully automated sensor calibration

- Enables compliance with FDA21 CFR Part 11 guidelines

- PC communication with USB or RS232

- Load set-ups, store study data and upgrade firmware via USB or Floppy

- Network installation/management – fully automatic management of passwords, audit trail and data files

- New common reporting software for Validator®, RF ValProbe® and ValProbe®. Added flexibility and convenience in merging data files from multiple Validators®, RF ValProbes® and ValProbes®

- Powerful graphing tool during reporting with Report Wizard, showing all sensors and samples through a complete study

- New Report Wizard allows now to select lethality calculation also during reporting. Lethality parameters can be changed.

- Lethality output can now be given in seconds for A0 evaluation (disinfection)

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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 USB flash drive 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 drive allows loading set-ups, storing data and upgrading firmware via USB
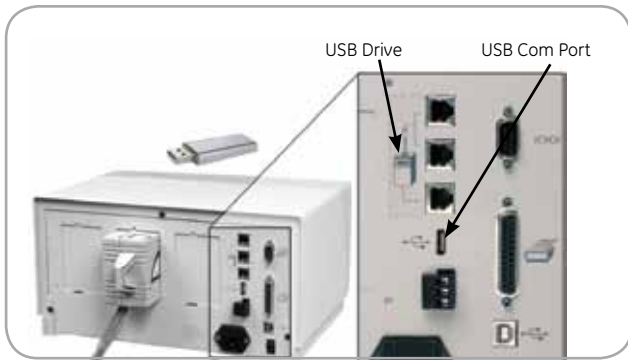
USB port allows direct connection between PC and Validator for downloading studies.

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.


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.
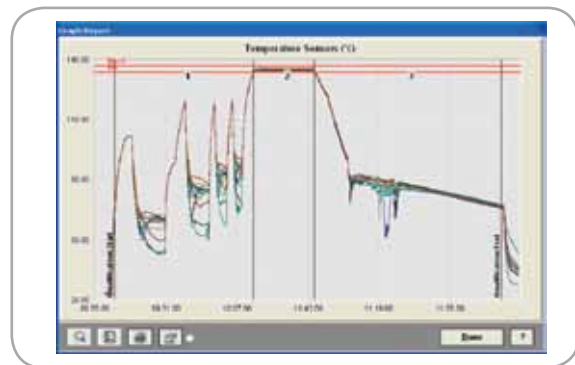
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