

Validator ® 2000

Benchmark Thermal Validation System

The Validator 2000 is a standalone thermal validation solution specifically designed to conform with new FDA data protection guidelines (21 CFR Part 11) and meet international and European cGMP requirements for inspection of pharmaceutical, biotechnology and medical device (EN285, EN554) manufacturing. The Validator 2000 simplifies the entire validation process by reducing setup time and minimizing sensor handling, automating sensor calibration, neatly organizing study data and generating regulatory required reports.



Meets FDA guidelines for protecting electronic data (21 CFR Part 11)

Prevents unauthorized access via user ID and password for critical operations

Creates secure results using files that cannot be used if tampered with

Creates printed or spreadsheet reports from a single protected file.

Creates comprehensive audit trail of all actions affecting user data.

Raw data is never modified

- Protects data with internal memory if floppy disk fills up or printer runs out of paper
- Saves data with battery back-up for up to 30 minutes if system loses power
- Plug-in Sensor Modules minimize sensor handling and save calibration time
- Eliminates the need for quick disconnects on each input
- Stores calibration offsets, allowing the software to link module with a specific instrument. From storage to instrument, sensors are ready for immediate use.

Most importantly, the Validator 2000 features a report generator that enables the grouping of calculations into customized, easy-to-read reports. The system organizes the test data in a spreadsheet format, saving analysis time and speeding access to critical process data.

Flexibility to operate standalone or with PC during testing

- Calibrates sensors and runs qualification studies with or without a PC
- Provides easy-to-read data for up to 12 sensors per screen with menu-prompted displays
- Enhances viewing on PC screens such as trending of live data

More flexibility to setup your test

- Separates sensors in up to four groups, e.g., independent reports for distribution and penetration or for qualifying multiple chambers
- Headers and comments are unique for each group
- Sets conditions for automatic starting and stopping of exposure and qualification
- Calculates lethality using base temperature, Z and D values
- Provides condition of lethality calculation based on chamber pressure
- Includes interval min., max., avg., and standard deviation calculations

Save time analyzing data

Generates new spreadsheet formatted reports for each group: easy to read

Creates Summary report to view test results at a glance

Simplifies tracking of validation data since all results of Setup, Calibration and Qualification are kept in a single protected file

Prints reports individually or all at once

Locates files quickly because they are saved by descriptive name, author and date

Monitors critical events and generates messages

Trends inputs and calculations on-line

No more hassles to document exceptions

Eliminates need to circle exceptions, write comments by hand, or use spreadsheet software to recalculate data

Documents a failed sensor, but user can exclude bad data from calculations

Captures user comments as part of standard report

And there is much more...

Accepts up to 36 inputs in any combination of thermocouple, voltage or current inputs

Provides total system accuracy of 0.28°C with improved noise immunity

Meets European requirements for fast data storage of one sample per second

Supported by fully validated hardware, software and firmware documentation

Simplifies your SOP development using 22-page standard operating procedure on disk

