

Core Technologies

Design Philosophy

For

Pharmaceutical Validation data loggers.

Core Technologies has identified two major application areas in the Pharmaceutical Industry, requiring different features in their Loggers. Accordingly Core Tech has developed two models of Data Loggers; Vali-DAQ and Pharm-LOG. Vali-DAQ is designed for short duration cycle data logging and Pharma-LOG is designed for continuous data logging over prolonged durations.

Vali-DAQ is designed to perform validation cycles on equipments like DHS, Autoclave, and Tunnel. Pharmalog is fine tuned to perform tasks of data logging for Cold Rooms, Deep Freezers, Stability Chambers and other long duration data logging requirements.

Both are Universal Input loggers with excellent accuracy of $\pm 0.2^{\circ}$ C over -100 to $+500^{\circ}$ C. Both incorporate high speed data capture, all the 16/32 Channels are acquired in less than one second. Vali-DAQ 512 Kilo Byte memory is divided in to 16 pages for storing 16 validation cycles. Pharmalog has all 512 KB for continuous data logging for days and months.

Both loggers feature Core Technologies popular Steam Trap Junction Box concept, which besides protecting the logger from steam leakage, also makes it easy to shift the logger from one application to another. Such re-deployment saves you investment and time.

Both loggers feature two tier password protection, one supervisor and three users with their IDs and separate passwords. Both loggers support signed metadata with traceable operations history,

including the latest addition under 21 CFR Part 11 viz. Imposter Trap – Alarm and record. Both models allow off line printing of the logged data and generate, at the end an Authentication printout with operator name and cycle history with space for hand signatures of the operator and the supervisor. This, by definition forms a "Hybrid System" which is, as per published data does not require 21CFR Part11 compliance certificate and is considered equivalent to open systems for Electronic data transmission over the internet which meet 21CFR Part 11 compliance. Notwithstanding the above, both the data loggers are designed to be absolutely tamper proof, using all modern features available in electronics like dynamic data encryption and data validity checks. Core Technologies data loggers are designed to guarantee validity of Electrical input calibration for minimum one year from the date of dispatch and cannot be calibrated by anyone else other than authorized Core Technologies Engineer. At the same time the loggers feature facility for sensor calibration using standard oil baths and Ice baths. Both models operate from 90 to 265 V AC input and consume less than 10 W power. Recommended operating temperature range is 20 to 30°C, however loggers can be operated at extremes of temperatures like 0 to 50°C without severe degradations to its specifications. Both loggers are available in SS314 enclosure as well as powder coated MS enclosures.

Vali-DAQ data loggers work under Coster Windows® XP software for generation of F0 and Fh reports, with graphic and tabular reports.

Pharma-LOG works under Core Technologies Scan-VU software also under Windows environment. "Scan-VU Super" generates tabular reports with MKT calculations. The table on the next page gives a comparison of Validaq and Pharmalog data loggers.

Features	Pharma LOG v2	Vali-DAQ
Number of Channels	Recommended 32 Channels 16 Channels Optional	Recommended 16 Channel 32 Channels Optional
Target Applications	Cold Rooms, Deep Freezers, Stability Chambers	DHS, Autoclave, Tunnel, Incubator
Templates	Only one setup.	Four pre-defined Templates for DHS, Autoclave, Tunnel, Incubator
Universal Input	Yes (K, T, E, J, Pt-100, Pt- 1000, 1V, 10V, 4-20 mA, 0-20 mA)	Yes(K, T, E, J, Pt-100, Pt- 1000, 1V, 10V, 4-20 mA, 0-20 mA)
21 CFR Part 11 Compliance Features	Yes (Audit Trails, Imposter Proof, Imposter Log, Password Protected Operation)	Yes (Audit Trails, Imposter Proof, Imposter Log, Password Protected Operation)
Auto logging	No	Yes, Data Storage starts after a preset temperature is reached in any one channel.
Serial Upload	On-Line each scan and Off- Line full data	Off-Line full data only.
Printing	On-Line and Off-Line	Only Off-Line
Windows Software	Scan View (Online Serial Upload)	CoSTER (Only offline for Validation Report generation)
Display options	Auto Scroll or Lock on to a selected channel	Auto Scroll or Lock on to a selected channel.
Global Sensor Calibration	Yes, (only for temperature sensors)	Yes, (only for temperature sensors)
Instrument Calibration	Hard Programmed cannot be altered in the field	Hard Programmed cannot be altered in the field
Tamper -Proof	Absolutely	Absolutely