Core Technologies

CERTIFICATE OF COMPLIANCE

(US FDA Regulation 21 CFR Part 11)

1. **The Hybrid System:**

   i. The US FDA Regulation 21 CFR part 11, defines Hybrid electronic systems as “Electronic Instruments capable of generating printed paper records of the logged data, in Real Time either online or offline, through a Printer connected to such an instrument. Records printed on such a system have provision for authentication by the operator and supervisor by affixing their hand signatures." As per published documents on 21 CFR Part 11, such hybrid system does not fall under the purview of the Regulation.

   ii. Core Technologies Data Logger Pharma-LOG 100v2 and Vali-DAQ in 16 or 32 channel configurations provide real time on line printing of logged data, on an external dot matrix printer connected to the data logger with track-ability information included, in the Header (meta data) with links to all pages of the report, appended by an additional “ authentication sheet" with the provision for affixing hand signature of the operator and the supervisor. While the two data logger models stated above fall in the category of “Hybrid Systems”, Core Technologies has exercised additional care to ensure proper operator track-ability, design rules and the specifications traceability and interlocks to make the instrument tamper proof.

2. **Traceability:**

   a. Core Technologies certifies that their Data Loggers Pharma-Log 100v2 and Vali-DAQ are designed and manufactured to prevent any attempt to disturb or tamper with the basic calibration of the instrument in the field, by the operator.

   b. Core Technologies guarantees the validity of basic calibration for a period of 1 year from the date of shipment.

   c. Core Technologies certify the calibration of the data loggers with the supporting certificate copies of calibration of the equipments/instruments used, with their respective

calibration certificates signed by the original manufacturers or by an NABL approved laboratory.

3. **Track-ability:**

a. Core Technologies Data Loggers, Pharma 100 and Vali DAQ are designed with hard coded program to operate under two levels of passwords. Both the products are closed systems (Only runtime) and are secured using these two level password features.

b. The Supervisory Password:
Supervisory Password is communicated in writing using secret code to an authorized senior executive of the purchaser of the Core Technologies Data Loggers. This password is hardcoded and the purchaser has to ensure secrecy of this password. The supervisory password authorizes user to define three operator level IDs and passwords at the second level. Core Tech recommends periodic changes in the second level Passwords.

c. Operator Password:
The operator passwords along with user ID of operator are to be defined by the supervisor using supervisory password. Features available under Operator Password are described below:

i. Programming of real time clock (RTC) is allowed under only supervisory password. Audit trail log of this action is stored in the memory for later verification.

4. **Keyboard:**

i. After power on all keys of instruments are "dead" (except [Auth] and [Unlock] keys). [Auth] key allows supervisor to assign unique user IDs and Passwords to operators. Using [Unlock] key authorized operator can enter valid User ID and password to proceed further with normal operation of instrument.

ii. In the event of no key operation for a period of 60 seconds, instrument goes automatically in to locked mode and user has to re-enter ID and Password.

iii. Imposter trap (latest addition to 21 CFR Part 11)

The Data Logger Key-board locks permanently with audible alarm after 3 failed attempts to start or stop the logging operation. This event is also tagged with valid Time and Date stamp and stored in the memory for future reference. Logger can be restored to the normal operation only by acknowledgement at Supervisor level.

5. **Meta-data and other information**:
   i. Data logger keeps track of cycles by numbering them sequentially. This Number is stored in the data logger for life and is be linked with all validation reports uniquely. Meta data information can be entered through keyboard of the data logger. Meta data includes Company Name, Plant Info, Operator User ID, Batch Info, Product Info and is printed on the first and last page of the printed report generated on the printer connected to the instrument either on –line or off-line.

6. **Data encryption:**
   Core technologies data loggers use strong encryption methodology to upload the data from logger to the PC for analysis under CoSTER software or SCANVIEW. Each data logger is uniquely linked with serial number of the instrument and the serial number of software. The data storage on the pc, in raw data form is encrypted and hidden. The archival support is only storage of final validation reports including graphic, tabular and print screen versions of records. The raw data is archived in encrypted form.

7. **Data Transmission:**
   a. Electronic data transmission post report generation does not fall under the purview of Core Technologies Data Loggers and the user must ensure secure data transmission over the internet or any other media using features available in the open domain.

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