

TELEDYNE ANALYTICAL INSTRUMENTS

UV CLEAN: Real time cleaning validation

The monitoring and control of active residue, during and after the cleaning of pharmaceutical or food and beverage process equipment, is an important part of the cleaning validation procedure. Costs associated with a cleaning, such as remediation of cleaning solution, increased use and disposal of cleaning solvents/detergents, and production turnaround, continue to rise. The low-cost, real time cleaning monitoring and control system from Teledyne can be applied to either batch or continuous processes. TAI uses UV technology to detect trace residues in various cleaning solutions throughout the entire cleaning process. Use of this UV technology will help end users reduce the cleaning cycle time and total cleaning solution volume used.

Benefits of the TAI System

The single most important objective is to implement a control strategy that effectively maintains company assets by increasing production through reduction of wash time between product batches. Benefits of this strategy are:

- Reduced use of solvents, i.e. Methanol
- Continuous monitoring of residue in wash cycle to determine when cleaning is finished
- Ability to monitor multiple target residues
- Fixed or mobile system
- Single vendor product

Data Management System

At the heart of the cleaning validation system is a recorder that records the signals from the UV detectors in accordance with the FDA's 21CFR11 electronic records, electronic signatures final ruling.

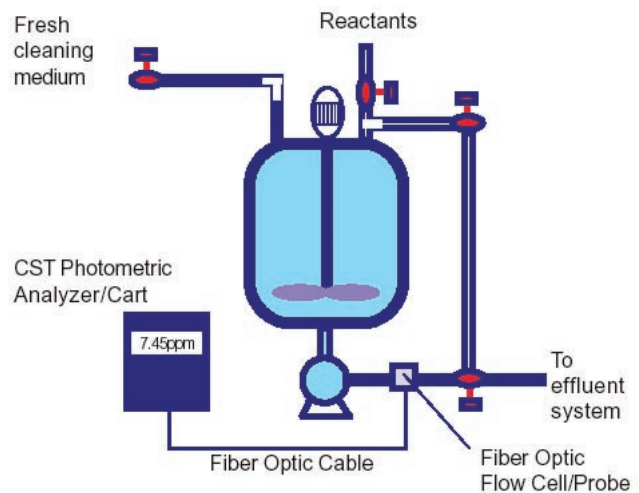


5320-CV Mobile UV cart and recorder

Communication with the system can be via ethernet, TCP/IP, or mobile phone. The system saves data as secure, binary encrypted files. Log in functions require user name, user ID, and password.

Electronic signatures can be applied to the electronic records by using the secure log-in and record signing functions.

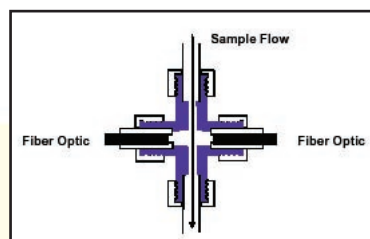
System Overview



Sample Interface

Teledyne can offer either an extractive sample flow cell or retractable insitu probe to interface with the process fluids. The flow cells or probes can operate at high pressures and temperatures up to 220°C. The probe's construction is 316SS and it is supplied with silica or sapphire windows. Since fiber optics couple directly to the probe or flow cell, there is no concern with electrical components in contact with potentially explosive vapors or liquids.

Note: For more information regarding electronic records / electronic signatures, please read the FDA final ruling in the Code of Federal Register, 21CFR11.



Fiber Optic cross flow cell



Fiber Optic cross flow shown with sanitary fitting



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PRODUCT SPECIFICATIONS

System

Ambient temperature: -10 to +50° C
Measured parameter: UV absorbance of active residue, other optical regions available, consult factory
Electromagnetic compatibility: per IEC 801, CE standards
Repeatability / accuracy: ±1% full scale
Sensitivity: ±0.005 AU
Response time: 1 to 10 seconds depending on sample transport time to detectors

Data Acquisition (designed for 21CFR11)

Electronic records: Save in secure, binary format (cannot be altered)
Audit trail: DX-P saves all settings and operations in same file with data
System access: DX-P can register up to 30 users configured to utilize a 3 combination code
System security: 2 admin levels, 30 users, user privilege assignments, auto log out, password exp configuration
Electronic signature: DX-P allows the application of e-signature; name, date, time.
Communication: DX-P network enabled data acquisition and display
- High resolution color display with ZIP or PCMCIA flash card
- Ethernet interface with FTP, web server, and email support
Compliance: IQ / OQ / PQ validation protocol; assessment testing to 21CFR11 regulation

Optical

Light source: UV-VIS Lamp (Xenon, Deuterium, or Tungsten Halogen)
Filters: Interference or absorption
Detectors: Si, PMT, InGaAs, or PbS
Wavelength range: 200 - 2150 nm
Fiber optic connectors: SMA-905, fiber length up to 100M (wavelength dependent)
Calibration: NBS traceable reference filter (manual or remote trigger)

Electrical

Power requirement: 24 VDC, 110 / 220 VAC, 60 / 50 Hz, 500mA
Signal output: 4-20mA (isolated), adjustable over the concentration range
Signal loop resistance: 600 Ohms, maximum

Mechanical

Analyzer Electronics

Size: 24" x 30" x 12" Nema-4X / IP65 purged and suitable for Class 1, Div 2 areas

Weight: 52.5 lb.

Fiber Optic Flow Cell / Probe: 316SS, with pathlengths from 1mm up to 50cm, consult factory

Application

Measured parameter: 1-4 active residues
Concentration: ppm and percent ranges (application specific)

Options

UV Channels: Up to four total

Other measured parameter: pH, conductivity, ORP, flow, temperature

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Warranty

Instrument is warranted for 1 year against defects in material or workmanship. NOTE: Specifications and features will vary with application. The above are established and validated during design, but are not to be construed as test criteria for every product. All specifications and features are subject to change without notice.

