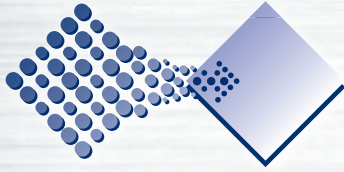


# On-Line Cleaning Validation

## Real Time Cleaning Validation



The monitoring and control of residual material during and after the cleaning of pharmaceutical or food/beverage process equipment is an important part of the cleaning validation procedure. Costs associated with cleaning such as remediation of cleaning solution and production turnaround continue to rise. The real time cleaning, monitoring, and control system from Custom Sensors & Technology can be applied to either WFI, ultrafiltration, or CIP processes. CST uses a suite of optical technologies (UV-VIS, NIR, IR) to detect targeted trace materials of interest throughout the entire cleaning process. The goal of our program is to increase your production by reducing the time needed to clean vessels.

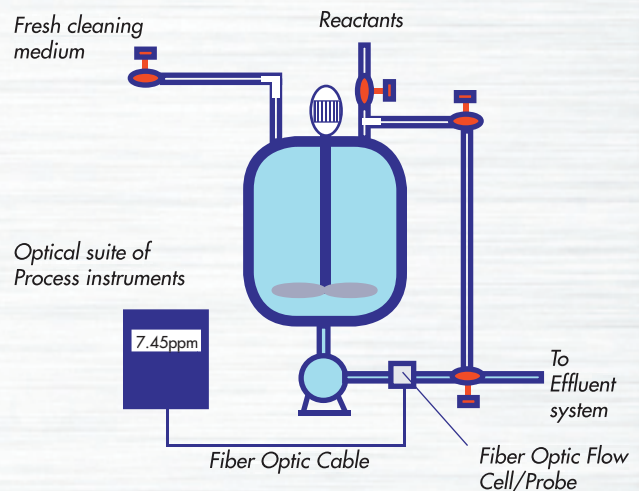
### Insuring proper time savings

Pharmaceutical and food/beverage facilities are continuing to see increased demands on production and have begun to experience capacity limitation in the plant due to excessive cleaning of vessels or improper time management. CST addresses these issues with an initial *Gap Analysis* study of your cleaning procedures. We audit your overall current cleaning procedures and based on the types of compounds you produce we make recommendations as to what analytical tools to incorporate into an on-line, portable, cleaning monitoring system. In addition, we provide a *Gantt Chart* that will identify time savings steps that can be incorporated into your cleaning procedures that will also help save time.

**Turnaround time savings as high as 50% have been realized by some customers!**

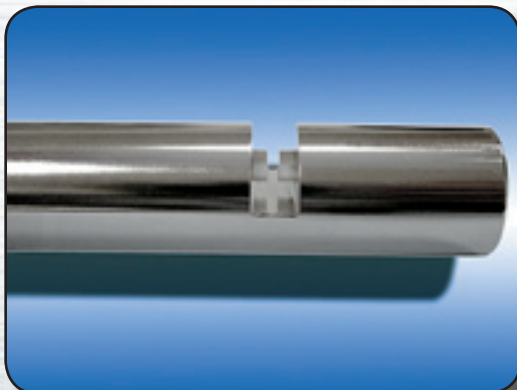
### System Overview

Typical recirculation cleaning installation.



### Sample Interface to Process Stream

CST can offer either an extractive sample flow cell or insitu probes that interface with the process fluids. The flow cells or probes can operate at high pressures and temperatures up to 220°C. Probe construction is 316SS and 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 and the sanitary design prevents potential contamination of the solution.



*Insitu Process Probe with 2mm pathlength*



*Extractive sanitary flow cell*

*Custom Sensors & Technology is a manufacturer of process photometric and electrochemical based process transmitters.*

## Mobile Cart



5320-CV CST Mobile UV  
Cart & Recorder

A mobile cart can be supplied to integrate with all the analytical instruments needed to monitor the rinse solution from your tanks. Carts can be supplied with UV-VIS, NIR, or IR spectrometers systems. Determination of one or multiple spectrometers is based on the original Gap Analysis.

## Data Management System

At the heart of the cleaning validation system is a recording device (PC or recorder) that records the signals from the optical detectors in accordance with the FDA's 21CFR11 electronic records (audit trail), electronic signatures final ruling. Optional communication with the system can be via Ethernet, TCP/IP, or mobile phone. 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.

## Benefits of the Monitoring System

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

- Reduced use of solvents, i.e. Methanol and high purity water such as WFI
- Reduction in volume of waste products to process
- Continuous monitoring of residue in rinse cycle to determine when cleaning is finished
- Ability to monitor multiple target residues with Spectrometers that range from UV to IR
- Monitors cleaning of membrane filters
- Potential reduction of scale/beer stone formation in breweries
- Fixed or Mobile system

## Specification of System

Items to be specified will depend on the initial investigation of customers analytical requirements, software/operator interface requirements, electrical requirements, flow cell/probe requirements, fiber optic cable requirements, documentation requirements, and commissioning and training requirements.

Please consult factory;

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Custom Sensors & Technology is a full service supplier. In addition to the cleaning validation systems we also supply photometric analyzers, fiber optic probes & flow cells, O<sub>2</sub> transmitters, sample handling systems, and services including: application engineering, commissioning & start-ups, and in-house repair services.