SpectrAlliance, Inc.

Fiber-optic spectroscopy for process control and laboratory automation

NOVA

- *The Nova UV-VIS-NIR process spectrometer system is designed for process control and laboratory automation environments. Real-time analysis of the process stream facilitates instantaneous verification of product composition and quick product changeover.*

- *Up to twelve process components may be monitored per channel, and a system may comprise multiple channels. Components may be measured directly, or predicted from a chemometric model.*

- *The Nova's modular design allows you to specify a system tailored to your particular application. A full range of lamps, spectrometer modules, and chemometric modeling options is available.*

- *Unique NovaPAC software makes even the most complicated procedure a quick and simple matter. System security and calibration are equally straightforward.*

- *The stainless-steel enclosure is designed to with stand even the harshest environment. Purge and cooling units may be added to make the Nova system compliant with relevant regulatory requirements.*

- *Ethernet or modem communication capability simplifies archiving and transfer of data, and allows remote control of the system*

- *Display of data is controlled by the user. Select display range, time trending parameters, and specify process components.*

- *Multi-channel operation increases the flexibility of the Nova system. You may designate an active reference channel and take simultaneous measurements in various process locations, or monitor additional process components.*

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Spectrometer Systems

- *Data logging of both spectra and component values for archiving or off-line analysis. Offline analysis ability facilitates process and protocol developments and evaluations. Real-time chemometric modeling available.*

- *Comprehensive model and system diagnostics ensure the validity of the system, and predict maintenance intervals.*

- *Output options include 4-20 mA outputs configurable for discrete or data model indicators. Alarm relays are selectable as either system-wide or individual component alarms. Fieldbus and Modbus communication protocols are supported. Output options also include OPC and DDE communications.*

- *FDA 21 CFR part 11 and GAMP compliant*

- *Fiber-optic accessories for accurate measurements.*

Touch-screen communication allows you to configure parameters, run methods and log data.

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Cleaning Verification with the Nova Process Spectrometer

Introduction

Production equipment when off line is little more than a sophisticated redundancy system, anchoring your facility to earth in case of sudden gravity failure. And yet, down-time is inevitable–reactor vessels must be cleaned from time to time.

Medieval winemakers sent small boys armed with scrub brushes into their vats. Cleaning methodologies have evolved since then, but time-based rinse cycles with large volumes of solvent are now as archaic as tool-toting orphans.

Clean-in-Place Technology

Spectroscopic Clean-In-Place (CIP) techniques reduce the time required to meet FDA and GMP guidelines by as much as an order of magnitude. Off-line HPLC is replaced by real-time analysis of the cleaning solution. The rinsing cycles can be ended as soon as a zero-change state is reached, reducing not only the time necessary for changeover but also the consumption of wash solvents.

Characteristic UV-Vis spectral features may be identified in the cleaning solution when it contains the pharmaceutical active ingredient. The spec-trometer system is calibrated (via linear regression or a more sophisticated chemometric model) against known concentrations of that active ingredient. When the concentration of the ingredient in the solvent reaches a pre-defined level of acceptability (typically <10 ppm), the reactor is considered clean.

The Nova cleaning verification process

First, a method is developed for the cleaning cam-paign, which specifies all measurement and config-uration parameters. Method development sets the Nova for optimal detection of the ingredient and defines output and display requirements.

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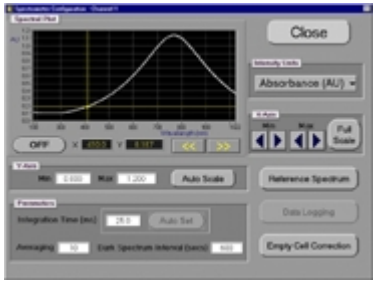
Cleaning Verification with the Nova Process Spectrometer

When the method is executed and the verification process begins, the cleaning solution is monitored by the Nova with fiber-optic probes or flow cells. The spectral information collected is used to calculate concentration values according to the predefined model. The results are displayed and communicated to the DCS.

Once a method is developed, it may be archived and recalled upon demand.

All elements of the system–spectrometer modules, light sources, sampling devices, and chemometric modeling software–are orchestrated by the NovaPAC operating system, and may be controlled via the touch-sensitive screen on the front of the Nova enclosure, or by ethernet communication.



The Spectrometer Configuration screen allows you to set the operating parameters for the spectrometer module.

Data collection process is defined so as to best report the spectral features of interest.

The run screen displays the data collected during a process, and reflects the parameters set on the configurations screens.

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Fiber–Optic Accessories

Every SpectrAlliance probe is custom built to meet the user's specific environmental and process requirements. If you do not see the instrument you need among those we currently offer, please ask for a design quote. OEM inquiries welcome.

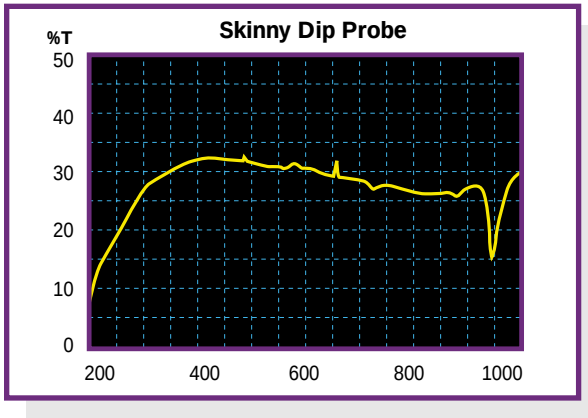
Dip Probes

SpectrAlliance dip probes measure UV, Vis, or NIR absorption. Designed for use in either process stream or laboratory situations, each SpectrAlliance probe is built to meet the customer's unique temperature, pressure, and corrosion-resistance requirements. Configurations are available for use by hand, or via robotics, tube fitting, or ball valve.

Our unique Skinny Dip probe measures only 4 mm in diameter, a size especially convenient in dissolution monitoring.

Dip Probe Options

Probe Diameter: 4 mm, 6.3 mm, 12.8 mm
Optical Path Length: 2.5 mm, 5 mm, 10 mm or specify
Optics material: fused silica, sapphire
Body Material: 316SS, Hastelloy, Techtron PPS, titanium
Body Length: specify
Fiber: 600µ core, silica/silica, NA=0.22
Optical Fiber Length: specify
Fiber Connection: SMA, ST, FC



The graph shows typical transmission of a UV optimized, 4mm dip probe in air.

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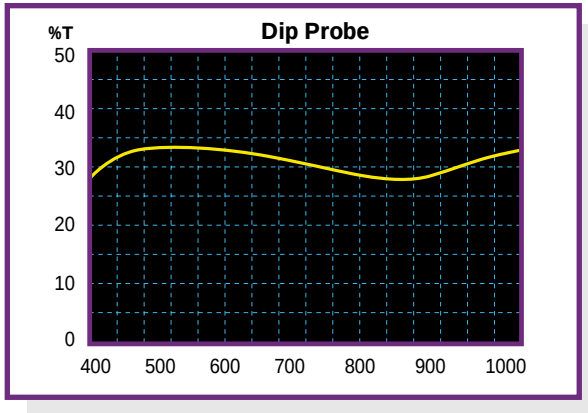
Fiber–Optic Accessories

Polymer Melt Probes

Designed for use with the Rheometric Scientific melt-measurement platform, SpectrAlliance polymer probes comprise a pair of optical probes in an optical cartridge. The probe windows are sealed in the optical cartridge to ensure the leak-tight integrity of the probe.

SpectrAlliance polymer probes feature replaceable sapphire windows, ensuring high throughput over the long term.

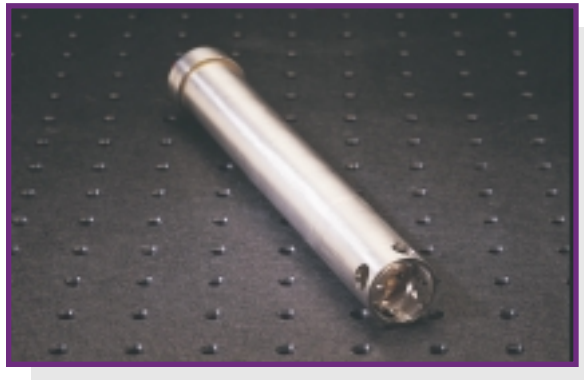
Optical path lengths for the probes are determined by cartridge configuration.



The graph shows typical transmission of an NIR optimized, 6.3mm dip probe in air.

ATR Probes

SpectrAlliance Attenuated Total Reflection (ATR) probes measure UV, Vis, or NIR absorption in opaque or viscous liquid samples. They are equally effective in process and laboratory environments. Sapphire optics and mechanical seals ensure performance in high temperature and pressure applications, and in aggressive chemical streams.



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