

NIR spectroscopy

PAT solutions

for manufacturing solid-dose pharmaceuticals

Sentronic – great technology, great advice, great commitment

SentroPAT FO



SentroProbe DR LS

Customizable one-stop solutions for process analysis **Robust, powerful, proven**



A complete solution, a customizable solution.

Sentronic solutions for process analysis comprise the SentroPAT FO platform, the probes and the corresponding analyzer management software. The result is a powerful, proven package that can be tailored to your specific process-monitoring needs.

SentroPAT FO is a compact analyzer for direct monitoring of production processes for solid-dose pharmaceuticals. It is an extremely versatile system that can be quickly and easily integrated into existing production equipment and processes. It offers extremely valuable insights into practically all process steps, such as blending, granulation, drying and compressing. It delivers precise data in real-time on input materials, process progress, product homogeneity, and the ideal process endpoint. The combination of high-speed measurement and highly robust, innovative probe technology creates an exceptionally reliable tool for improved process understanding and measurement.

The NIR advantage

NIR infrared spectroscopy is the most versatile PAT technology available, with a proven track record in laboratory applications. It can be deployed to capture both physical and chemical process parameters, often rendering additional particle measurement equipment unnecessary.

Fast diode array technology

This specific NIR technology is ideal for analyzing fast-moving samples, without compromising accuracy. Measurements can be performed in milliseconds, allowing the prompt elimination of spectra with poor sample presentation.

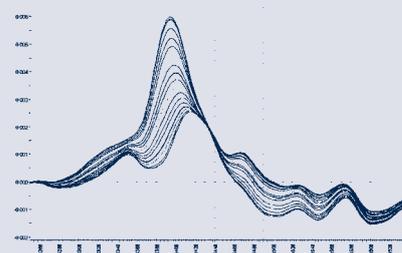
Low maintenance

A key focus of design and development from the very outset was minimum maintenance effort and cost of ownership. The system continuously and automatically monitors all key instrument parameters, operating reliably for extended periods without user intervention. The only regular maintenance required is light source replacement, generally at intervals of one to two years. This simple task can be performed without special tools or skills.

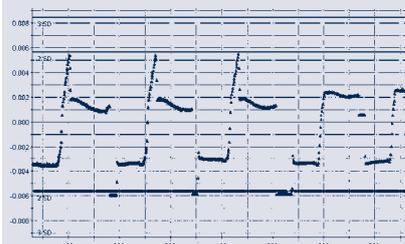
Partnership with Sentronic

Sentronic has implemented end-to-end, fully compliant documentation across the entire product life cycle for many customers, and for many projects. We are an experienced, flexible partner. We understand that each customer has specific needs and imperatives, and we develop made-to-measure answers to the challenges of each PAT project. We are happy to play a supporting role within your existing organizational structures, providing vital input. You can be sure of effective communications, and quick, easy access to expert advice.

From high quality spectra to significant process data



NIR spectra from high-shear wet-granulation process



Trend diagram for five wet-granulation processes, PCA, first principle component over time

Photos at bottom of page:

1. Thanks to internal referencing directly at the probe window, the system displays exceptional stability.
2. The process window is heated, maximizing visibility even when the pharmaceutical product adheres to equipment.
3. The two pre-adjusted light sources can be easily replaced by non-expert users.
4. The innovative probe concept enables precise and cost-effective multi-channel operation. This allows simultaneous monitoring of multiple unit operations or of multiple product lines.

SYSTEM COMPONENTS



1



2



3



4

SentroPAT FO main unit

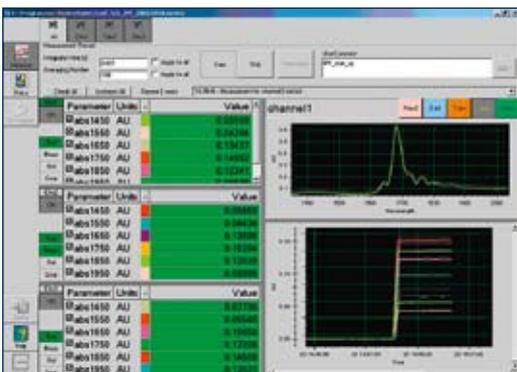
At the heart of this PAT solution is a high-performance diode array spectrometer, a fast channel multiplexer and a high-performance embedded PC running Windows XP. Monitor, mouse and keyboard can be connected for configuration, servicing or tests. Ethernet connectivity and an internal OPC server are provided for the process environment. The compact, GMP-friendly unit can be installed directly in the production area. Smooth surfaces and the IP65/ NEMA4 enclosure mean quick and easy cleaning. Probes can be placed up to 50 meters from the analyzer without any significant impairment of performance. Simple single-fiber cables can be used in place of expensive bundles.

SentroProbe DR LS

Excellent probe design ensures high signal throughput and large spot size. Nevertheless, measurement times of 1 second are typical. A choice of probe lengths and a compact enclosure allow easy integration into diverse production equipment configurations, and positioning at the most suitable measurement points. Sentronic can design and manufacture complete process interfaces, where needed. The robust probe is designed to withstand harsh conditions, including machine vibration and temperature fluctuations.

SentroSuite GmP

This user-friendly GmP and 21 CFR part 11-compliant software package was developed within the scope of close cooperation with a number of customers in pharmaceuticals. The package is designed to maximize the benefits of Sentronic analyzers. Integrated interfaces to third-party chemometric applications, such as SIMCA and Unscrambler, allow you to use the modeling software of your choice. SentroSuite GmP includes an audit trail, comprehensive user management, file and data security, and other features suited to the needs of the pharmaceutical industry. Full IQ/OQ/PQ documentation can be provided in line with your specific needs.



Technology	Multiplexed diode array spectrometer with 4 measurement channels
Wavelength range	1100-2200 nm (full specification within 1150-2150 nm)
Wavelength accuracy	± 1 nm over full specification range
System noise	≤ 50 µAU RMS within 1150-2150 nm at 1 s measurement
Embedded PC	Intel Atom based, Windows XP professional
Communication	Ethernet (OPC, UDP, TCP/IP)
Housing	GmP friendly (smooth surfaces), IP65 / NEMA4
Dimensions	160 x 220 x 240 mm
Operating conditions	10° ... 30°C, 10% ... 90% relative humidity

Spot size	5 mm diameter / 20 mm ² surface
Light source	2 internal 5W bulbs for redundancy Lamp modules user replaceable Lifetime 14,000 hrs
Internal reference	Internal micro-mechanical white reference direct at window
Process window	Welded in Sapphire
Probe shaft	¾" / 19 mm diameter, length 65, 100, 200, 300 or 500 mm
Approvals	ATEX zone 20/21, CE
Self monitoring	Internal controller and sensors to monitor probe function and status
Operating conditions	0° ... 80°C probe tip up to 150°C for CIP processes

Data pre-treatment	Poor spectra rejection, mathematical pretreatments noise monitoring
Analyzer management	Health Status monitoring, data security, user management, audit trail
Chemometric interfaces	Simca QP, Unscrambler, GRAMS
Technology	.NET based application
Communication protocol	Ethernet based UDP, TCP-IP and OPC server
21 CFR Part 11 compliance	Full accordance with requirements to electronic records
USP<1119> EP 2.2.40	Supporting complete test procedure, generation of validation protocols



Sentronic has been successfully developing and manufacturing optical sensors and analyzers, primarily for chemical parameters, since 1993. The company's core technologies comprise optical spectroscopy and optical chemical sensing. Our main product lines are innovative optical oxygen sensors and NIR process analyzers, including in-house-manufactured sampling interfaces and versatile analyzer management software. Sentronic markets its technology and solutions to end-customers in the life sciences and chemical industry, and to OEM and private-label customers.

Sentronic has been serving the pharmaceutical industry for many years. The organization enjoys strong relationships with major pharmaceutical players, collaborating closely in the realm of product development. This has resulted in two product lines based on diode array NIR and tunable laser technology, focusing on solid-dose manufacturing. These solutions offer significant advantages. Development efforts are ongoing, and in particular address new PAT challenges.

Sentronic has implemented a life-cycle model in line with GAMP. With the assistance of external auditors, Sentronic has

created a database-oriented documentation system that complies fully with all applicable pharmaceutical standards and regulations. It has been designed for flexibility, and can accommodate new industry requirements and technology enhancements.

An additional strength is the design and deployment of industry- and customer-specific solutions. Furthermore, Sentronic enjoys a unique skill set, with many years' experience of spectrometer systems and probes, combined with in-depth knowledge of pharmaceutical production processes. As a result, we lead the way in the development of high-performance analyzers that are exceptionally robust and stable under real-world process conditions.

Sentronic's core competencies

- ▶ Fiber optical and optical design
- ▶ Optoelectronics and optomechanics
- ▶ Functional and optical coatings
- ▶ Instrumentation design and development
- ▶ Probe design, including deployment in hazardous environments
- ▶ Software development (for PCs and embedded hardware)
- ▶ Feasibility studies
- ▶ Chemometric modeling



Sentronic is located in the beautiful city of Dresden, Germany. While we are only too happy to visit your company, you are welcome to visit our facility, where we can discuss your challenges in detail, and jointly develop a made-to-measure solution.

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