



New!

Diode-array-based NIR analyzer
for pharmaceutical powder blending

SentroPAT DA

SentroPAT DA is a dedicated NIR analyzer for non-invasive online monitoring of pharmaceutical powder bin blending. The system provides valuable process insight from product development to operations and can also be used to control blend time. This extremely compact system with its very low weight fits many sizes of blenders.

High performance diode array spectrometer

The heart of the instrument is a rugged and proven InGaAs diode array spectrometer. High spectral resolution and wavelength accuracy combined with low noise enable the use in demanding applications. Superior system-to-system comparability simplifies method transfer between instruments. Long-term wavelength and temperature stability is achieved through the use of proprietary internal standards.

Understand and control the blending process

In addition to determining the blending end-point by statistical methods, it is possible to also perform quantitative analysis of the potency of APIs or other blend constituents using chemometric models. Based on the process knowledge gained through NIR analysis, it is possible to optimize blend time, avoid faulty batches and prevent segregation due to over-blending. There is no longer a need for conventional sampling and laboratory analysis, which impede manufacturing processes

and therefore raise production costs. Fully implemented and applied, the online monitoring of blend uniformity is a key element for real-time release.

Flexibility and easiest handling

Focus areas of design and development from the very outset were ease-of-use and minimum maintenance time :

- ▶ Mounting to the blender is done by means of a simple 2" or 4" sanitary flange.
- ▶ Recharge the battery using the system's power adapter.
- ▶ The internal 3-axis accelerometer allows

software adjustable and reliable measurement synchronization to the blender rotation.

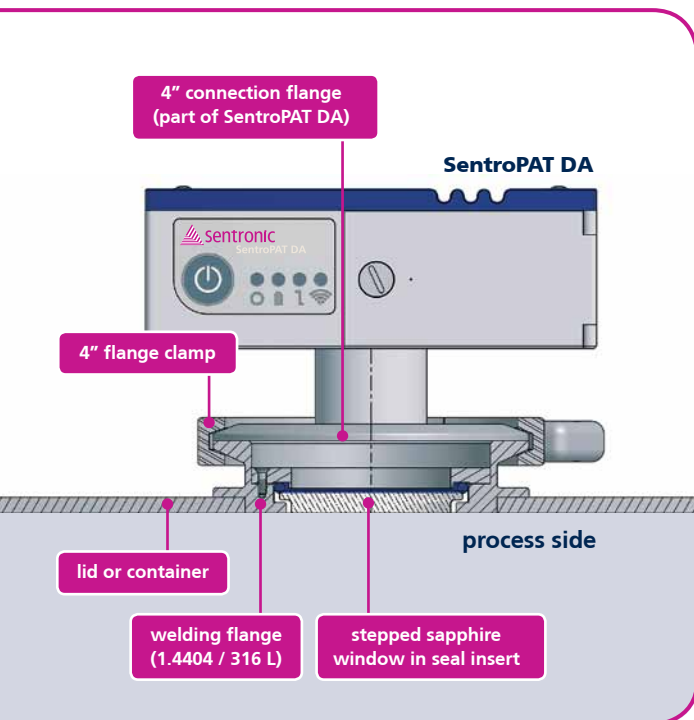
- ▶ The smooth surfaces of the unit can be easily cleaned, as it is required for use in GMP production facilities.

Highest data integrity

Data integrity is supported by the embedded system, where all generated data are buffered locally on the analyzer, before transmission through the WiFi connection. The system supports integration to plant level IT and controls via OPC-server or interfaces to SIPAT or SynTQ.



The system provides easy access to the battery.



The process connection is made by a separate process flange with an integrated sapphire window. This flange is welded into the bin wall or into the bin lid. The inside surface is flush to process side thus there is no impedance to the material flow.

Technical Parameters

Detector	512 pixel linear InGaAs array
Wavelength range	1 100 – 1 900 nm
Spectral resolution (FWHM)	approx. 10 nm
Wavelength accuracy	< 1 nm
Wavelength reproducibility	< 0.2 nm
Internal reference	Internal intensity reference
Photometric linearity	Fulfilling USP<1856> and EP 2.2.40 requirements
Noise – High flux	according to USP<1856> and EP 2.2.40
Noise – Low flux	according to USP<1856> and EP 2.2.40
Light source	2 x 5W used redundantly, maintenance-free
Data acquisition time	< 1 s (configurable, typically 0.5 s)
Sampling interface	Non contact, through sapphire window
Measurement spot size	approx. 10 mm diameter
Measurement trigger	software controlled by 3 axis accelerometer, synchronized to blender rotation
Power supply	replaceable Li-Ion battery, > 6hrs operation External power supply (24VDC) for lab operation and recharging
Enclosure	IP65 / NEMA4, cGMP conform, Aluminum anodized
Dimensions	170 x 105 x 60 mm (W x D x H) Height: add 36 mm for flange
Weight	2.2 kgs including battery
Communications	WiFi (802.11 a/g/n)
Software	SentroSuite GMP on external PC
Validation	Software integrated validation routines according USP<1856>, EP2.2.40
Mounting	4" or 2" sanitary flange

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Since 1993, **Sentronic** has been successfully developing and manufacturing optical sensors and analyzers, primarily for chemical parameters. With our core competence in photonics, the combination of optical technologies and microelectronics, we supply high-tech products combined with comprehensive services. Our focus is on the development and manufacturing of complete optical sensor and analyzer solutions for the pharmaceutical, chemical and life science industry. We provide flexibility in customizing as well as OEM products. The business unit analyzer is a partner for NIR based PAT solutions in the pharmaceutical industry with a strong focus on solid dose manufacturing processes.

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.