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A turnkey solution for
pharmaceutical powder blending

SentroPAT BU II

SentroPAT BU II is a dedicated on-line solution for the monitoring of pharmaceutical blending in bins. The NIRS-based turnkey solution can provide valuable process insight at every stage of development and can even be an input for RTRT. Due to its compact size and low weight, the system can be easily mounted to a wide range of blenders and containers.

High performance MEMS spectrometer

The heart of the instrument is a tunable laser-based MEMS spectrometer. High analytical sensitivity is achieved by the combination of superior optical resolution and low noise. Outstanding system-to-system comparability simplifies method transfer between different blender types, processes and instruments.

Control the blending process

Besides determination of blending end point by statistical methods, quantitative analysis of API and other formulation ingredients by applying chemometric calibrations is possible, too. Based on the additional process knowledge, it is possible to optimize blending time, avoid faulty batches and prevent blends from being segregated due to over-blending. There is no longer need for conventional thief sampling and laboratory analysis, both of which delay manufacturing. Fully implemented and applied, the online monitoring of blend uniformity can be one key element for real-time release.

Flexibility and ease of handling

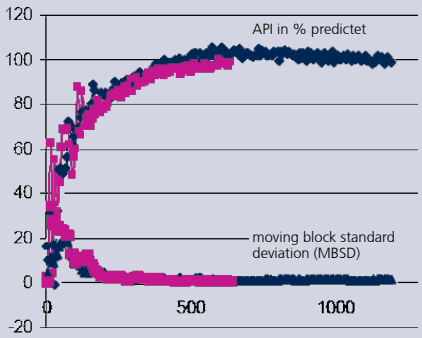
A key focus of design and development from the very outset was ease of use and minimum maintenance effort:

- Mounting can be done by means of a simple 4" hygienic flange
- Hot swappable batteries and internal, as well as external charger, provide outstanding battery life for wireless operation for at least 5 hours of use
- The 3D orientation sensor allows software adjustable and reliable measurement synchronization to the blender rotation.
- The housing of the system can be easily cleaned, as required for use in GMP production facilities.

Ensure data integrity

Measurement data integrity is ensured by the use of an internal PC running Windows 10. All data are stored locally on the analyzer, before transmission through the wireless network. Standard PC peripherals can be directly attached for service or IT administration. Wireless Ethernet connectivity and an OPC server are provided for communication in the process environment.

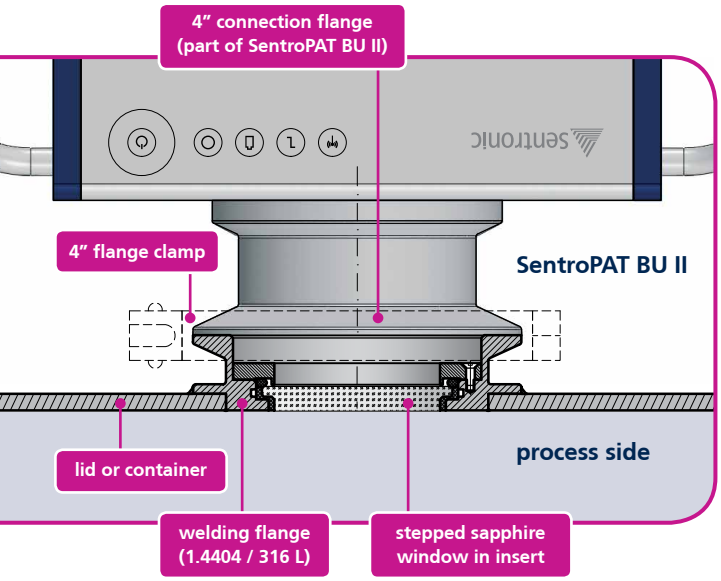
Measured blend profile



NIR blend uniformity allows to optimize blending time (pink curve)

IBC equipped with SentroPAT BU II



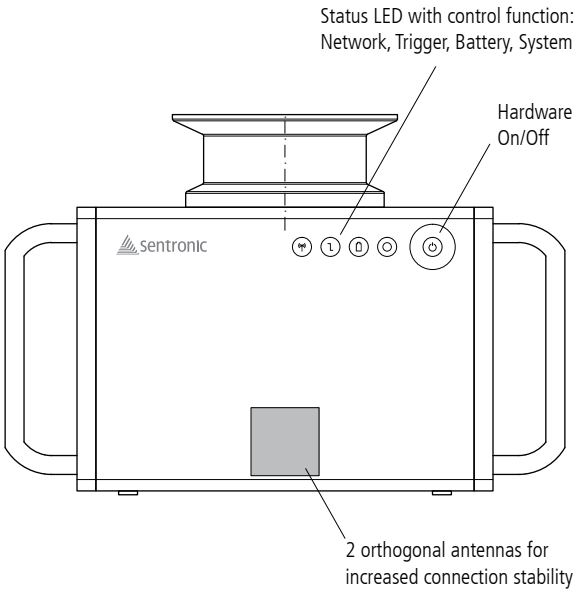


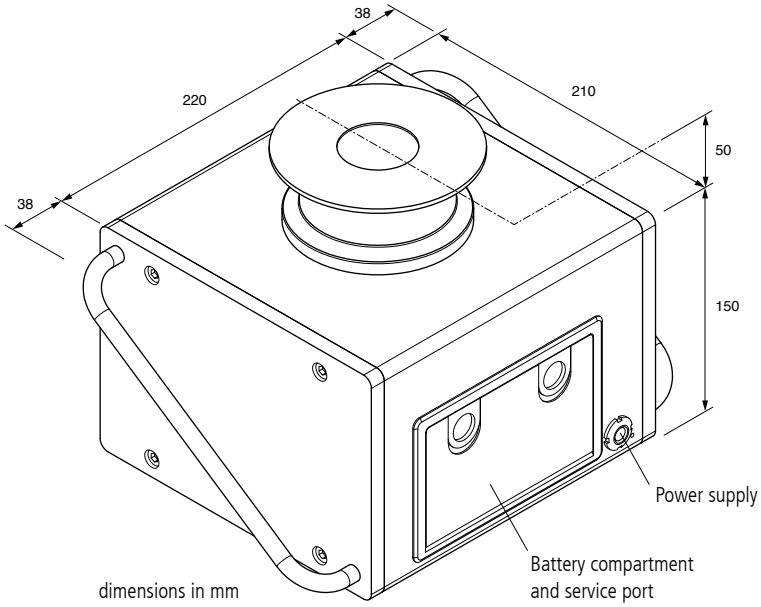
The SentroPAT BU is attached to a bin using a separate flange with an integrated sapphire window. This flange is welded into the bin wall or into a modified bin lid. The surface to the process is flush by design and thus there is no impedance to material flow or change in blending behavior. Sentronic has worked with many customers and major pharmaceutical bin manufacturers to successfully modify bins and bin lids for a wide range of equipment.

Technical Parameters

Wavelength range	1350 – 1800 nm
Optical resolution (FWHM)	≥ 0.3 nm (configurable); specification at 2 nm
Compliance	USP<1119><1856> / EP 2.2.40
Sampling interface	Non contact, through sapphire window Different flanges available as accessory
Measurement spot size	25 mm nominal with approx 18 mm covering 90% of signal
Working distance	Depending on Sapphire window (27 mm at 8.5 mm Sapphire)
Embedded PC	Intel Quad Core 1.6GHz, 4GB RAM, >200 SSD Windows 10 Professional LTSC
Power	Hot swappable battery with ≥ 5 hrs operation Integrated battery charger and external power supply
Enclosure	IP56 / NEMA4, cGMP friendly design
Dimensions of complete system	220 x 210 x 150 (+50)[1] mm / 8.7 x 8.3 x 6 (+2)[1] inch [1] length of process flange
Weight	7.5 kg / 16.5 lbs
Measurement trigger	Internal software controlled 3D position measurement
Communications	Wireless LAN (802.11 a/g/n)
Software	SentroSuite GmP
Validation	Software integrated validation routines
Service port	Connections for DVI-D and 3 x USB
Mounting	4" hygienic tri-clamp

Details, Dimensions





dimensions in mm

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