

NanoRam®-1064



The NanoRam-1064 is a state-of-the-art handheld Raman instrument for nondestructive identification and verification of incoming raw materials such as APIs, excipients, and intermediates. Compact and agile, the NanoRam can be used by non-technical users to rapidly identify samples in the lab, warehouse, loading dock or field, helping to eliminate quarantine areas and expedite materials through the manufacturing lifecycle. Utilizing Raman technology, analysis can be performed through transparent containers, all while maintaining the volume and integrity of the sample. The high-performance NanoRam-1064 minimizes fluorescence, and can differentiate different grades of cellulose, polysorbate and Opadry®.

The NanoRam is fully compliant with all governing regulations, including 21 CFR Part 11 and Part 1040.10, and plays an integral role in cGMP-compliant facilities. The NanoRam-1064 meets the requirements of Raman spectroscopy methods including the US Pharmacopeia <1120>, European Pharmacopeia 2.2.48, as well as the People's Republic of China Pharmacopeia Guidelines on Raman Spectroscopy. Raman is a well-recognized method for compliance with the PIC/S & GMP guidelines regarding 100% identity assurance for starting materials. B&W Tek offers a wide variety of services, including method and/or new library development support as well as IQ/OQ/PQ/DQ implementation services.

Data Quality & Reproducibility

- Robust hardware provides high quality data with low noise, providing consistent and reliable results with fast measurement times. Even samples that have high fluorescence signal with most Raman systems can be identified with the NanoRam because of the 1064nm laser excitation.
- Method and library transfer between devices for company-wide deployment
- User-definable methods and libraries to meet particular analysis needs
- TE cooling allows for greater stability of the instrument in environments where temperatures are highly variable.
- On-board method validation
- Secure data transfer and database to ensure data integrity

Versatility in Sampling

Easy Transition Between Sample Types

The NanoRam includes a variety of sampling accessories optimized for the measurement of various materials in the form of liquids, gels, powders, or solids under both a laboratory setting and demanding environmental conditions. The NanoRam is designed to facilitate fast and convenient transitions between sample adaptors.



Contact Immersion Probe



Point & Shoot



Vial Holder



Polystyrene Validation



Right Angle Adaptor



Bottle Adaptor

Specifications

Excitation Wavelength	1064 nm
Laser Output Power	420 +/- 30 mW at 100%, adjustable in 10% increments
Spectral Range	176 cm ⁻¹ to 2500 cm ⁻¹
Display	High brightness & high resolution touch screen
Barcode Reader	1D and 2D standards
Software	NOS-1064 (embedded), NID EX (PC)
Data Formats	.txt, .csv, .spc
Data Transfer	Wi-Fi, & USB
Battery	Rechargeable Li-ion, >4 hrs continuous operation
Weight	~ 3.4 lbs (1.545 kg)
Size	9.8 x 4.3 x 2.4 in (250 x 110 x 60 mm)
Operating Temperature	-10°C to +50°C
Protection	IP65
Sampling Accessories	point & shoot, vial holder, polystyrene validation cap, contact immersion probe, large bottle adaptor, right angle adaptor

Easy Operation for Non-Technical Users

- Touch screen interface with simple 1-touch workflow
- Easy single-handed operation
- Batch mode for quick testing of multiple containers
- Interface available in multiple languages
- Camera barcode scanner for quick method selection and for sample photos
- LIMS compatible



Intuitive Software

State-of-the-Art Identification Software

The NanoRam is operated using B&W Tek's intuitive NOS-1064 embedded software. The touch screen interface allows for identification and verification, library and method development, method validation, and data storage/transfer. The NanoRamID EX (NID EX) software is designed for use on PCs for data and methods management in a secure database, allowing customers to review data, generate reports, export data, and integrate to their LIMS system. NID EX provides a complete audit trail for instrument operations and electronic report signing. The NanoRam ID EX and NanoRam OS EX software packages are 21CFR part 11 compliant with IQ/OQ/PQ/DQ documentation and services available.

Additionally, the NanoRam provides secure Wi-Fi and USB synchronization capabilities with network terminals in order to optimize time and resources. NanoRam OS EX is capable of data and report transfers in order to centralize information (such as libraries, methods and final reports) in general servers.

The NanoRam provides robust algorithms for identification and verification of samples. The p-value from a multivariate classification method on the NanoRam is the best way to verify materials. These robust methods are based on multiple sample spectra, thus providing representative sampling of multiple samples/lots of material and the ability to include the natural material variation. It also includes mixture analysis capabilities to identify multiple components in a sample.

The NanoRam includes a library of 110 USP standard pharmaceutical materials.

