B&W TEK
Your Mobile Spectroscopy Partner

NanoRAM
HANDHELD RAMAN SPECTROMETER

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, so can effectively identify many more materials, even those with color. The NanoRam-1064 can differentiate different types 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, Japanese Pharmacopoeia 2.26, as well as the People's Republic of China Pharmacopeia Guidelines on Raman Spectroscopy. Raman is a well-recognized technology 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 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-1064 with its 1064nm laser excitation.
- 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 and library 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

Large 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

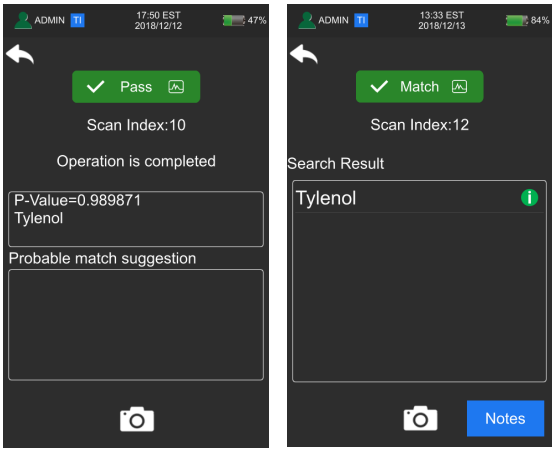
Easy Operation for Non-Technical Users

- 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
- Barcode scanner for quick method selection and product information entry
- LIMS compatible

Intuitive Software

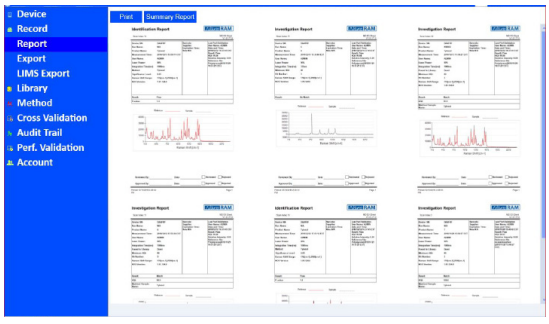
State-of-the-Art Identification Software

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 and validation, and data storage/transfer. The PC-based NID EX software for data and methods management in a secure database, allows 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 The NID EX and NOS-1064 software packages are 21CFR part 11 compliant with IQ/OQ/PQ 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. Analysis information can be centralized by using NID EX, and transferring data and reports to store libraries, methods and final reports in general servers.

The NanoRam provides robust algorithms for identification and verification of samples. The statistical p-value from a reduced variable multivariate method on the NanoRam provides the best way to verify materials with a pass/fail result. These robust methods are based on multiple sample spectra collected from representative samples/lots to include natural material variations. Mixture analysis is also available for identification of multiple components in a sample.



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

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