

## NanoRam®

### Handheld Raman Spectrometer



The NanoRam 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, indirect-contact analysis can be performed through transparent containers, all while maintaining the volume and integrity of the sample.

The NanoRam meets the requirements of Raman spectroscopy methods including the US Pharmacopeia General Chapter 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. The NanoRam is fully compliant with all governing regulations, including 21 CFR Part 11 and Part 1040.10, and can play an integral role in cGMP-compliant facilities. 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 weak Raman signal can be identified with the NanoRam because of this high dynamic range system.
- Broad spectral range as low as  $176\text{ cm}^{-1}$  for more spectral data to improve identification capabilities
- 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.

### 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 under demanding environmental conditions. The NanoRam is designed to facilitate fast and convenient transitions between sample adaptors.

The NanoRam has a unique immersion probe that comes standard with the instrument allowing for easy measurements of materials in bottles and drums beyond the surface. A disposable protective sleeve is available to prevent cross-contamination. We also have a shoulder bag to reduce stress on users when working long shifts, increasing portability.

Vial Holder



Point and Shoot



Bottle Adaptor



Shoulder Bag



Right Angle Adaptor



Tablet Holder



Immersion Probe



## Specifications

Excitation Wavelength	785 nm
Laser Output Power	Up to 300 mW, software adjustable
Spectral Range	176 cm <sup>-1</sup> to 2900 cm <sup>-1</sup>
Spectral Resolution	~ 9 cm <sup>-1</sup> @ 912 nm
Detector Type	TE-cooled Linear CCD Array
Display	High Brightness & High Resolution OLED Touch Screen
Barcode Reader	Linear and 2D Standards
Software	NOS (Embedded), NID (PC)
Data Formats	.txt, .csv, .spc, .pdf
Data Transfer	Ethernet, Wi-Fi
Battery	Rechargeable Li-ion, >5 hrs Continuous Operation
AC Adapter	Output: DC 12V, 2A Minimum
Weight	~2.5 lbs (~1.2 kg)
Size	8.8 in x 3.9 in x 2.0 in (22 cm x 10 cm x 5 cm)
Operating Temperature	-20°C to +45°C
Storage Temperature	-30°C to +60°C
Rating	IP64
Standard Accessories	Point & Shoot, Vial Holder, Polystyrene Validation Cap, Immersion Probe, Large Bottle Adapter

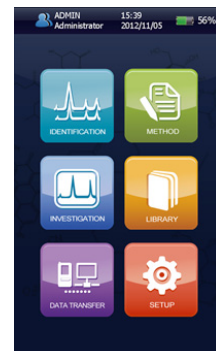
## Easy Operation for Non-Technical Users

- 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
- Compatible with Labware LIMS

## Intuitive Software

### State-of-the-Art Identification Software

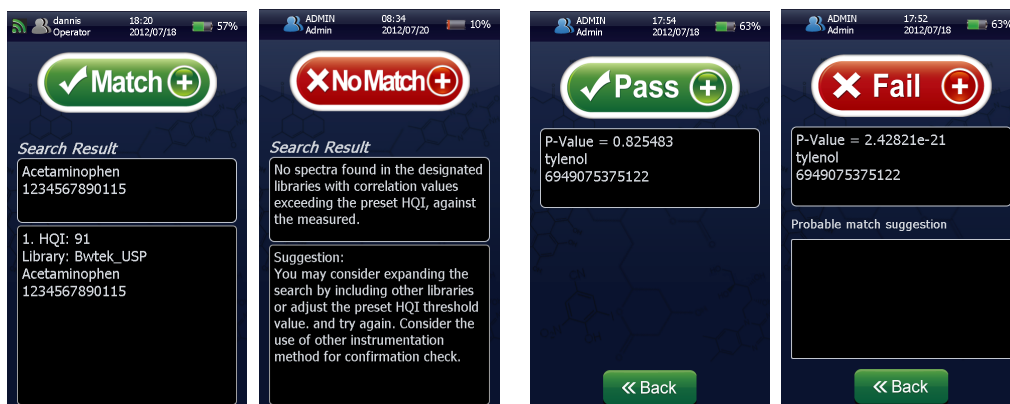
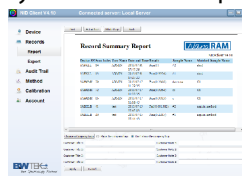
The NanoRam is operated using B&W Tek's intuitive NanoRam OS (NOS) embedded software. The touch screen interface allows for identification and verification, library and method development, and data storage/transfer. The NanoRam ID (NID) software is designed for use on PCs for data and methods management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



Additionally, the NanoRam provides secure Wi-Fi and Ethernet synchronization capabilities with network terminals in order to optimize time and resources. NanoRam OS 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 reflect 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.



### Investigation

### Identification