



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-1064 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 it can effectively identify even more materials including colored samples. The NanoRam-1064 can differentiate different types of cellulose, polysorbate and Opadry[®]. The unit also offers full onboard library and method validation, library and method transfer, saving users time when activating new methods and library entries on the device.

The NanoRam-1064 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 <858>, European Pharmacopeia 2.2.48, Japanese Pharmacopeia 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 challenging analysis needs
- TE cooling allows for greater stability of the instrument in environments where temperatures are highly variable.
- Secure data transfer and database to ensure data integrity

Versatility in Sampling

Easy Transition Between Sample Types

The NanoRam-1064 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-1064 is designed to facilitate fast and convenient transitions between sample adaptors.









Vial Holder



Polystyrene Validation



Large Spot Adaptor (optional)

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 |
| Camera | Can be enabled/disabled at Factory |
| 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, immersion probe, bottle adaptor, right angle adaptor, large bottle adaptor*, large spot adaptor* |

* optional adaptors"

Intuitive Software

State-of-the-Art Identification Software

The NanoRam-1064 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-1064 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-1064 provides robust algorithms for identification and verification of samples. The statistical p-value from a reduced variable multivariate method on the NanoRam-1064 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-1064 includes a library of 110 USP standard pharmaceutical materials for reference only.

Easy Operation for Non-Technical Users

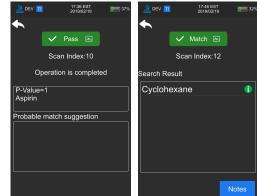
- Touch screen interface with simple 1-touch workflow
- Easy single-handed operation
- Batch mode for quick testing of multiple containers
- Interface available in multiple languages
- Barcode scanner for quick method selection and product information entry
- LIMS compatible

•

.

•





| Record | Mattileation Report | BRITE RAW | Investigation Report | MARGINE R.A.M. | Investigation Report | RAINTS RAM |
|------------------|--|---|--|--|--|---|
| | | *7775 | | *7.75 | | *725 |
| Report | Antonia ante herata Artera en herata Artera en herata | Inter National Units | Annual An | the Sector Sector | And an and | the Box diffe |
| Export | Annual and Annual Annua | National Statements National Statements | Number of States | ter Schedule Sc | Reported from prevent mapping | The Art of |
| LIMS Export | Register Trained Register and Million Spectrame Land Million Spectrame Land Million | wite of | Segurar Sector Stars | ***** | Register Society Million Reserved Texason Reserved Texason Reserved Texason | era-of |
| Library | Antonia in the | | arrest them | | Ross Richards - Hans Scholar 1 Richards - 10 Mill | |
| Method | Reads Frage Finalise 11 | | State Arbeit | | And And Mark II Market Inter | |
| Cross Validation | 5410 1010 | | 22) | | Ann the local | |
| | - 11 | 6 | | | | |
| Audit Trail | The stand | d. | | | - I.I. | |
| | | 10 10 10 | The second secon | any an are | - Walder Mr. | A |
| Fert. Validation | Ranac Bridge | | | | | |
| Perf. Validation | Rear Public | el. | | | No. 40 AL AND ADDRESS | 41 00 40 1 |
| | fase to be | | | | The second secon | |
| | teach in | Dense Dense | book bs | | Area Dify | Dense Dense |
| | teenty in | | Agreently are | Dense Dense Dense Dense | Annu Dely Annu Dely Annu Dely | |
| | teach in | Dens Dens | Annual Inc. | Denni Denni | Annu Selo | Deem Deem |
| Account | teenty in | Danas Danas Danas Danas Tapi | Agreently are | Dente Dente Text | Annu Dely Annu Dely Annu Dely | Dense Dense Dense Dense Dense Dense |
| | termity in magnetic termination of the second secon | Dense Danse Dense Danse Terr MUTTERAM | Approximation Report Topological States | Deres Deres | Necros | |
| | namely na | | Annohi Ini | Dent Dent Ter MOTORAM Kister | Arrento an Arrante Arr | |
| | kanashe Bo ayan ka Bo gan a kanashe a ayan kanashe a kanashe a ba a ayan ayan ayan ayan ayan ayan ayan | | Appropriate Applications (Constrained Applic | Depend Depend Tep: Record RAAM RECORD RECO | Angeleis Angele | |
| | hanning in a second sec | Dense Danse Dense Danse Terr MUTTERAM | reported to the second | Deres Deres | Augusta | |
| | Name Name | | revents as a constraint of the second | Depend Depend Tep: Record RAAM RECORD RECO | Augusta de la companya de la company | |
| | Kanana Kana Kanana Kanana Kana | | Terretta de la construcción de l | Depend Depend Tep: Record RAAM RECORD RECO | Augustation and a second and a | |
| | Name Name | | revents as a constraint of the second | Depend Depend Tep: Record RAAM RECORD RECO | Augusta de la companya de la company | |
| | A MARINA MARINA Terretaria | | Name Name International State State State State Name State | Depend Depend Tep: Record RAAM RECORD RECO | An and Party and | |
| | A MARINA Marina Marin | | Terretta de la construcción de l | Depend Depend Tep: Record RAAM RECORD RECO | A set of a | |
| | Annen de la constante de la co | Desc De | Name Name International State State State State Name State | Contraction of the second seco | An and Party and | Contract Department Contract Contract Department Contract Department Contract Dep |