Progeny™

THE NEW GENERATION IN HANDHELD RAMAN

REVOLUTIONIZE YOUR MATERIAL IDENTIFICATION

Rigaku
Rigaku Raman Technologies

PHARMACEUTICAL MATERIAL INSPECTION

With the push towards 100% inspection and lean manufacturing, pharmaceutical manufacturers are looking for efficient ways to reduce costs and risks associated with raw material identification (RMID), in-process analysis, finished product inspection and brand security, while complying with regulatory requirements. Traditional processes can include quality control (QC) lab analysis, a costly and time-consuming step especially when productivity must be optimized with fewer resources – and all without compromising quality. By implementing an identification method at the point of need with a tool that can be used by any employee, companies benefit from a process that is much more efficient and cost-effective. How can this be achieved?

Introducing **Progeny**™ – the first handheld Raman analyzer designed to be customizable for seamless integration into any work environment. Progeny delivers what truly matters in a customer's mind: error-free operation, repeatability, ease of use and the widest range of sampling capabilities – all in a handheld form. Progeny's open architecture software and data security features adapt to existing standard operating procedures (SOPs) or provide the flexibility in the creation of entirely new SOPs.

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TRADITIONAL RMID WORKFLOW:

1. UNLOAD
2. LABEL ID
3. QUARANTINE SHIPMENT
4. SAMPLING
5. SEND TO QA/QC
6. LOGIN
7. LABEL ID
8. MEASURE
9. IDENTIFY
10. REPORT
11. SECOND REVIEWER
12. RELEASE

May require a **few days** per batch

THE PROGENY RMID EXPERIENCE:

1. UNLOAD
2. LOGIN
3. LABEL ID
4. MEASURE
5. IDENTIFY
6. REPORT
7. SECOND REVIEWER
8. RELEASE

Typically achieved in a **few hours** per batch

COLOR KEY

- WAREHOUSE PROCESS
- OFF-LINE LAB PROCESS

GLOBAL COMPLIANCE: REDUCE RISK

All aspects of pharmaceutical manufacturing must comply with rigorous standards to ensure the consistent production of safe and effective drugs. As the pharmaceutical material supply chain continues to globalize, leading nations have imposed regulations that increase the amount of raw materials that require inspection.

Raman is an accepted spectroscopic technique by both the United States Pharmacopeia Convention (USP) and the European Pharmacopeia (EP). By combining Raman technology with a spectrometer that is small in size, easy to use, and produces high spectral quality, it makes it an ideal tool for material identification.

IS THIS MATERIAL WHAT IT IS SUPPOSED TO BE?

Handheld Raman spectroscopy is a technique used widely as part of the pharmaceutical manufacturing process to ensure the safety and efficacy of medicine by the analysis of:

- the standard of raw materials used in the manufacturing process
- the specification to which the final product is produced

Raw Material Identification:

- Active pharmaceutical ingredients (API)
- Excipients
- Nutraceuticals
- Pre-formulated materials and packaging

Verification:

- Pre- and post-clinical trial materials
- Chemicals and solvents

Authentication:

- Finished products
- Anti-counterfeit/brand security

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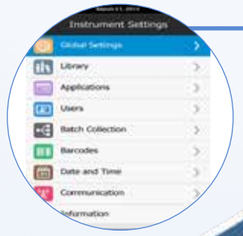
Smartphone inspired, touchscreen user interface:

Fast learning curve for easy implementation to customized workflow



Sealed system (IP-68):

Rugged warehouse use while minimizing cross-contamination

Optional docking station:

Transfer data while instrument is safely docked for continuous charge*

*Via USB, Bluetooth or WiFi

Adjustable focus nose cone:

Measure through thick polymer or dark glass

1064nm excitation laser:

Identify the most comprehensive range of material in a handheld form

Integrated digital camera and 21 CFR Part 11 compliant electronic signature:

Error-free data entry tracking & compliance

High-speed multi-function processor and on-board memory:

Flexible operation with on-board modern algorithms for accurate identification

Angled display with large-sized buttons:

Single hand operation for optimal usability

MORE VALUABLE RAW MATERIALS CAN BE INSPECTED

Fluorescence interference prevents successful chemical identification and analysis of some materials. When using 785nm or 532nm visible range excitation lasers, colored materials or colored containers can be a challenge with Raman. Users can now minimize fluorescence and broaden their analysis range because Progeny uses a **1064nm** high power laser in the near infrared range with high efficiency optics.

RAMAN-ACTIVE MATERIALS

Problematic Materials Easily Detectable with Progeny (partial list)

- Sodium carboxy methoycellulose
- Xantum gum
- Alginic acid
- Gelatin
- Indigo carmine
- Cell culture media
- Polysorbate 20
- Polysorbate 80

] In original bottles

Many common materials can be measured and detected by Raman handheld instruments. Metals, salts, and some packaging materials still represent a challenge to any type of Raman technology. Talk to your Rigaku Raman representative about your list of raw materials.

CELL CULTURE MEDIA IDENTIFICATION IN BIOPHARMACEUTICALS WITH PROGENY

Most cell culture media materials do not fluoresce with 1064nm excitation laser, therefore are quickly and reliably identified with Progeny.

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FEATURES AND ACCESSORIES

The evolution of handheld Raman analyzers continues. Beyond its revolutionary, ergonomic design and point-and-shoot functionality, Progeny adapts to pharmaceutical manufacturer's unqiue workflow processes and protocol by providing the following features and accessories:

Local control: benefit from flexible operation by manually using the touch screen and large buttons or remotely by PC or tablet using Bluetooth or wireless.

Libraries: factory and customizable library spectra for easy method development, deployment and centralized management

Docking station: recharge for uninterrupted operation, auto-synchronize data with LIMS, or conveniently use with sampling accessories for benchtop use

Adjustable focus nose cone: optimize sensitivity and signal per application by adjusting the focal distance

Sampling accessories: obtain accurate results from a variety of packaging materials and sample shapes




COMPLIANCE AND SUPPORT

Progeny is backed by a global network of sales and service support partners of Rigaku, offering installation qualification, annual preventive maintenance and prompt service assistance, when necessary.
Visit www.rigakuraman.com to find your nearest distributor.

- 21 CFR Part 11 compliance, including electronic signature
- IQ/OQ/PQ support and protocols
- Preventive maintenance
- Extended warranty programs

Rigaku Raman Technologies is a leading pioneer in portable and handheld Raman spectroscopy. We provide advanced analytical solutions that enable customers to achieve rapid, accurate results, at any time and in any place.

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