

Handheld Raman analyzer for material identification

With increased regulatory scrutiny, the rise of global supply chains and the drive toward lean manufacturing, pharmaceutical and biotechnology manufacturers must ensure the quality of materials throughout the process—from incoming raw material through finished product. The Thermo Scientific™ TruScan™ RM analyzer provides manufacturers with fast and accurate material identity verification with ease and convenience.

Applications

- Incoming raw material identity verification
- Dispensing of materials during API manufacture
- Counterfeit identification

Key Features

- Meets cGMP and 21 CFR Part 11 requirements
- Patented, embedded chemometrics engine
- Rugged design; chemical and drop resistant
- Weighs less than 2 lbs (0.9 kg)

The Thermo Scientific TruScan RM analyzer uses lab-proven Raman spectroscopy to perform rapid material identification at the point of need to decrease sampling costs and increase inventory turns. Designed for intuitive operation, its non-destructive point-and-shoot sampling principle facilitates rapid verification of a broad range of chemical compounds through sealed packaging to minimize the risk of contamination and exposure.

The TruScan RM analyzer is built with a state-of-the-art optical platform paired with a field-proven embedded chemometrics engine. Our patented, multivariate residual analysis offers the most effective chemometric solution for material identification – with two spectral pre-processing options, that is easy to operate in challenging environments and sampling conditions.

The analyzer's adaptive decision engine readily discriminates materials without the need for manual threshold setting or method maintenance. The embedded decision



engine collects not just the sample spectrum but also the measurement uncertainty at the moment of analysis, which allows the analyzer to adaptively adjust collection parameters to a wide variety of potential interferences (such as lighting, temperature and operator usage).

The TruScan RM analyzer also offers enhanced compliance features, as well as software and data management functions, designed to facilitate workflow and optimize efficiency in tightly regulated environments. Key benefits include:

Fast

Obtain PASS/FAIL results within seconds with an option for STRONG PASS/WEAK PASS and STRONG FAIL/WEAK FAIL on results. Method development is fast and simple, requiring minimal samples for creation of a robust model.

Compliant

Enhanced 21 CFR Part 11 compliance security features, such as biometric log-in and optional password aging and complexity, allow users to customize the analyzer's security settings to exceed regulatory requirements.

Broad Material Coverage

State-of-the-art optics and advanced chemometrics allow measurement of materials for which Raman analysis was either impractical or discrimination could not be achieved with traditional HQI (hit quality index).

Smart

Built-in smart features, such as assisted signature acquisition and device qualification warnings, ensure successful material identification and prevent user error.

Easy to use

User interface is easy to use and read. Improved functionality, including PDF batch reports and the option to synch the analyzer time clock to a PC time clock.

Lightweight

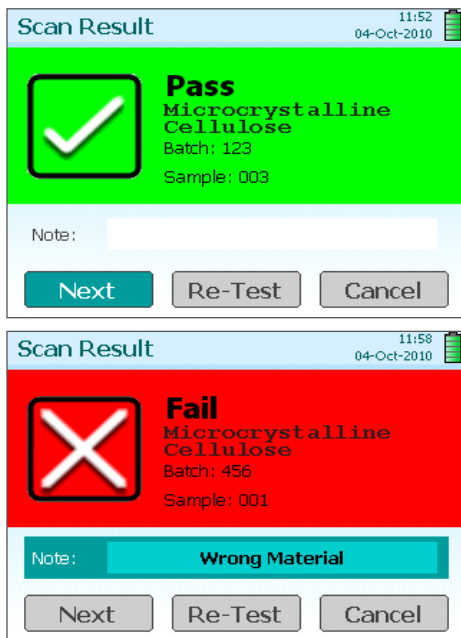
Weighing less than 2 pounds (0.9 kg), the analyzer is ergonomically designed to increase comfort and productivity during inspections.

Training and Support

Our subject matter experts provide training and technical consultation from method development and validation to general operator usage. Once up and running, we provide support anywhere in the world.

Prepared templates and documentation include:

- IQ/OQ/PQ
- SOP Templates
- Statements of Compliance



Once a measurement is complete, the analyzer provides a clear PASS/FAIL result within seconds.

Specifications

Raman Spectrum Range	250 to 2875 cm^{-1}
Spectral Resolution	8 to 10.5 cm^{-1} (FWHM) across range
Laser (excitation wavelength)	785 nm +/-0.5 nm, 2 cm^{-1} line width, stability <0.1 cm^{-1}
Laser Output Power	250 mW +/-25 mW
Collection Optics	NA=0.33, 18mm working distance; 0.2 to 2.5 mm spot size
Exposure	Automatic modes (12 ms minimum)
Battery	Rechargeable internal lithium ion battery > 3 hours operation
External Power Supply	DC Wall Adapter, 100-240 V AC 50/60 Hz
Weight	2 lb (0.9 kg)
Size	8.2 in x 4.2 in x 1.7 in (20.8 cm x 10.7 cm x 4.3 cm)
Operating Temperature	-20°C to +40°C (continuous)
Connectivity	Ethernet
Ports	Up to 10 simultaneous ports
Operating Systems and Browsers	Microsoft Windows 7,8,10, Internet Explorer 11, Edge 25; Google Chrome 51
Barcode Supported Symbologies	Most linear and 2D standards
Biometrics	Fingerprint reader for easy login
Measurement Accessories	Vial holder, universal tablet holder, cuvette holder
Compliance	FDA 1040, 21 CFR Part 11, CE certification, Ph. Eur. 8.7

No. America
Boston, USA

Central and So. America
Sao Paulo, Brazil

Europe, Middle East, Africa
Munich, Germany

Asia Pacific
Mumbai, India
Shanghai, China
Tokyo, Japan

sales.chemid@thermofisher.com

Find out more at thermofisher.com/RMID

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