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.

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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

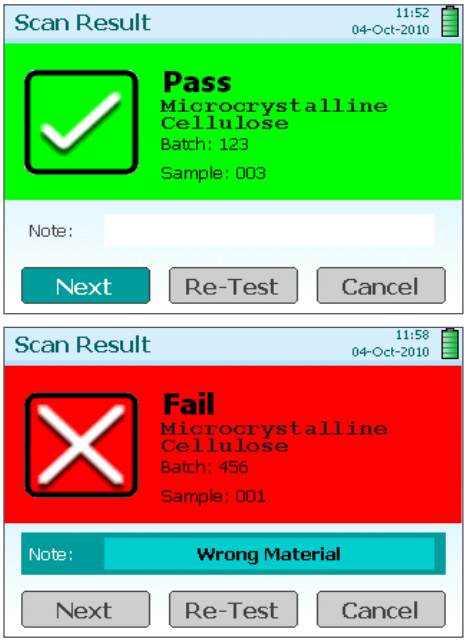
Weighing less than 2 pounds (0.9 kg), the analyzer is ergonomically designed to increase comfort and productivity during inspections.

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 x4.3 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

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Handheld Raman spectroscopy for qualitative and quantitative analysis

As the need to quickly identify and quantify more materials increases, pharmaceutical and biotechnology manufacturers require instruments that decrease laboratory sample testing and enable more at-line decisions. The Thermo Scientific™ TruScan™ RM analyzer with TruTools™ embedded chemometrics package provides users with the flexibility to build customized qualitative and quantitative methods for complex material analysis problems.

Applications include:

QA/QC

- Multiple component discrimination
- Coverage for additional raw materials
- Dosage form identification

PAT

- Solvent distillation
- Blend analysis and endpoint determination

Falsified/Substandard Medicines

- Better discrimination of authentic vs. falsified medicine
- API content quantification
- Identification of substandard medicines

TruScan RM Key Features

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

The TruScan RM analyzer is the foundation of the system, providing rapid and reliable material identity verification at the point of need. With its state-of-the-art optics and patented, multivariate residual analysis, the analyzer measures a broad range of solid and liquid materials. Method development is fast and simple, requiring minimal samples for creation of a robust qualitative model.

The TruScan RM analyzer with TruTools becomes a more powerful system, enabling users to create customized, advanced qualitative and quantitative methods for

deployment on the analyzer. No longer confined to the lab or benchtop spectrometer, users can conduct advanced chemometric analyses anywhere in the plant.

TruTools leverages Solo, a chemometrics software package from Eigenvector Research Inc. that allows users to develop models that can be deployed onto the TruScan RM analyzer as follows:

- Using TruScan RM with TruTools, the user customizes acquisition parameters including laser power, exposure time, and number of co-adds, then exports SPC files

- Once SPC files are imported into Solo, the user can define spectral range, preprocessing and algorithm type, then process data to generate custom models

- Using Eigenvector's Model_Exporter, Solo models are exported and deployed on the TruScan RM analyzer via WebAdmin

- Once deployed, TruTools methods are selected through standard menus on the TruScan RM analyzer

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The analyzer's embedded math engine runs customized models including:

Model	Type	Description
PLS	Quantitative	Supports quantification of up to 10 chemicals
PCA	Qualitative	Designed for pass/fail results based on a single class
PLSSQ	Qualitative	Suitable for putting limits on quantitative results; produces a pass or fail screen
PLSDA	Qualitative	Used to classify a group of chemicals or identify a chemical from a group of up to 10 chemicals; produces an identification screen

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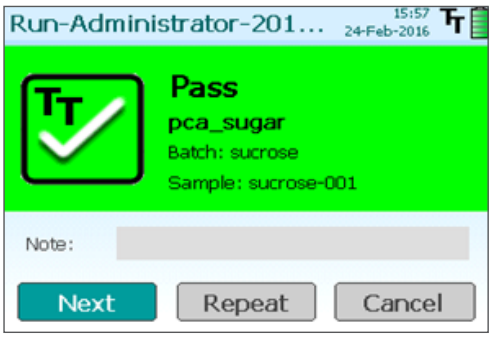
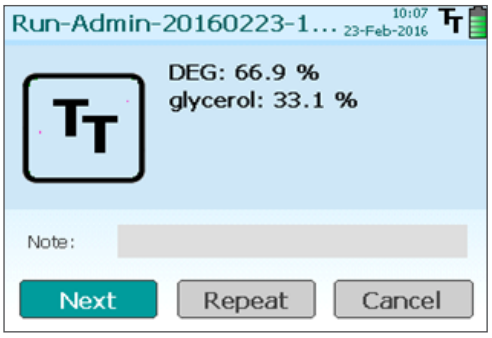


A PCA TruTools method screen result



A PLS TruTools method screen result.

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 or customizable (low/med/high) with TruTools
Collection Optics	NA=0.33, 18mm working distance; 0.2 to 2.5 mm spot size
Exposure	Automatic modes (12 ms minimum) or customizable up to 10,000 ms with TruTools
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 x4.3 cm)
Operating Temperature	-20°C to +40°C (continuous)
Connectivity	Ethernet
Ports	Up to 10 simultaneous ports
Software Version	Requires TruScan RM v.2.6 or later
Chemometrics Package	Works with Eigenvector Solo + Model_Exporter v8.1
Operating Systems and Browsers	Microsoft® Windows® 7,8,10, Internet Explorer® 11, Microsoft 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

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