Technical brief

TruScan RM and next generation TruScan G3 Handheld Raman Analyzers

Seamless Method transferability

The Thermo Scientific™ TruScan™ G3 Handheld Raman Analyzer is the next generation in Thermo Fisher Scientific's line of TruScan devices designed specifically for the pharmaceutical market. Core capabilities include 21 CFR 11 compliance with timestamp and user data integrity, and convenient handheld chemical identification at point of receipt thanks to Thermo Fisher's proprietary p-value decision algorithm.

The TruScan G3 Handheld Raman Analyzer has been designed with additional ergonomic and functional capabilities. The detachable probe allows the user to conveniently scan chemicals directly in bags or bottles, without prior sample collection before analysis. The capacitive touch screen enables convenient interface navigation with or without gloves. Data transfer may be performed wirelessly, or via a USB-C network adapter.

Users of legacy TruScan RM devices will be able to transfer Identification Methods directly to the new TruScan G3 Handheld Raman Analyzer. This provides a rapid and seamless way to avoid the need to recreate or devise new Methods for chemicals of interest on the next-generation instrument.

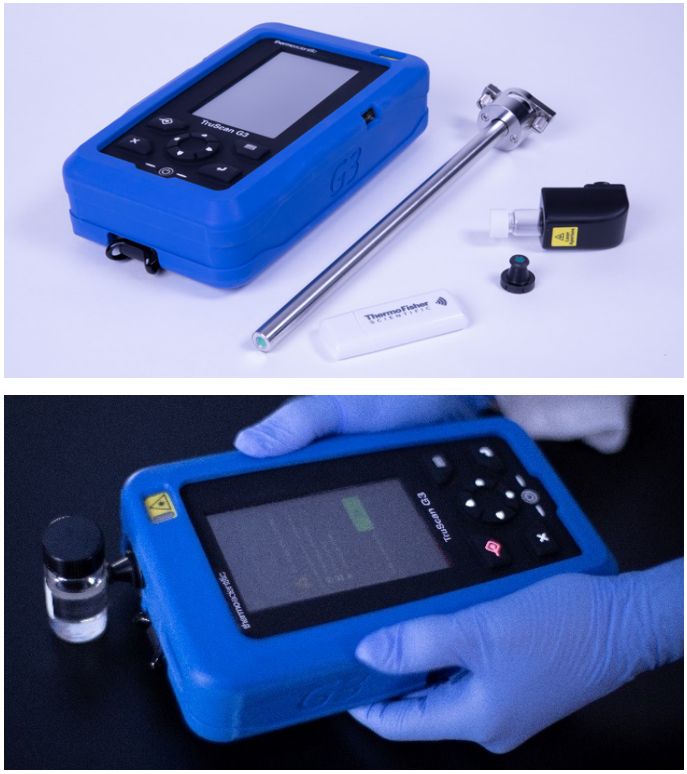

Figure 1. TruScan G3 handheld material identity verification system based on Raman spectroscopic technology - shown with accessories in top image.

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Method transferability has been extensively tested across a wide variety of chemicals with varying Raman scattering responses. (See Table 1.) Because this testing covered many chemicals that spanned the range from excellent Raman scattering to poor Raman scattering behavior, users can be confident that chemical identification Methods will provide accurate identification for their own use cases, regardless of which generation of instrument is used.

ID number	Test chemicals
1	Acetaminophen
2	Acetic acid
3	Acetylsalicylic acid
4	Calcium carbonate
5	Calcium stearate
6	Cellulose
7	Ciprofloxacin
8	D-Mannitol
9	Dibutyl sebacate
10	Diethylene glycol
11	Dimethyl succinate
12	EDTA
13	Ethylene glycol
14	Glycerol
15	L-Ascorbic acid
16	L-Glutamine
17	L-Histidine HCl monohydrate
18	L-Serine
19	Methanol
20	Mineral oil
21	Polydimethylsiloxane
22	Polysorbate 20
23	Polyvinylpyrrolidone
24	Potassium phosphate monobasic
25	Sodium bicarbonate
26	Sodium salicylate
27	Sulfathiazole sodium salt
28	Titanium (IV) oxide (anatase)
29	Alpha_Lactose monohydrate

Table 1. Chemicals used for Method Transfer capability testing between TruScan RM and TruScan G3 Handheld Raman Analyzers. These 29 chemicals were selected because they span the range from lower Raman scattering to high Raman scattering behavior.

Testing Method Transfer between TruScan RM and TruScan G3

Three legacy TruScan RM devices were used for Method Transfer, each with 29 chemical identification Methods created on the device, for the substances listed in Table 1. The serial numbers of these devices are TM1758, TM3038 and TM6594, referred to as “A”, “B” and “C”, respectively, in the figures below.

Three TruScan G3 Handheld Analyzers were used to receive a set of 29 Methods from each of these three TruScan RM instruments. The serial numbers of these devices are G3-401, G3-402 and G3-403.

Using three TruScan RM and three TruScan G3 Handheld Analyzers, nine Method Transfer data set combinations were created as shown below in Table 2. In this way, each TruScan G3 Handheld Analyzer used 29 Methods from each of the three TruScan RM devices, for a grand total of 261 chemical identification data points.

Nine data set combinations for Method Transfer testing			
	TruScan G3-401	**TruScan G3-402**	**TruScan G3-403**
TruScan RM-A	G3-401/A	G3-402/A	G3-403/A
TruScan RM-B	G3-401/B	G3-402/B	G3-403/B
TruScan RM-C	G3-401/C	G3-402/C	G3-403/C

Table 2. Nine data set combinations were made to test Method transferability from TruScan RM to TruScan G3 Handheld Analyzers. Each of the nine combinations shown in this table represents testing of the 29 chemicals listed in Table 1, providing 261 data points generated from Method Transfer from TruScan RM to TruScan G3 Handheld Analyzers.

The notation used to identify the data sets is shown in Table 2 is explained with the following example: G3-401/A.

- This example refers to Methods created on TruScan RM-A, with samples analyzed on TruScan G3-401
  - The 29 Methods created on TruScan RM-A were transferred to TruScan G3-401
  - The 29 test chemicals were then analyzed on TruScan G3-401 using the transferred Methods

The TruScan chemical identification decision algorithm uses the patented p-value methodology that statistically confirms or denies the spectral match of a sample spectrum to a Method spectrum within a specified amount of error. Any p-value < 0.05 will result in a FAIL (no-match) between the sample and Method spectra, while p-values ≥ 0.05 will result in a PASS (match), confirming the identity of the sample chemical to the Method chemical. Data shown in Figure 2 are for first derivative signal analysis.

The p-value data is all > 0.05 for all cases, indicating 100% PASS for every chemical identification across 261 chemical analyses. The red line at 0.05 in Figure 2 indicates the pass/fail threshold for positive chemical identification for the p-value statistical method.

Conclusion

The TruScan G3 Handheld Raman Analyzer has been designed to provide the user with Method transferability from the legacy TruScan RM device, saving time and effort by eliminating the need to make new Methods for the next generation of TruScan instruments. Adding a newer TruScan G3 Handheld Raman Analyzer to your fleet of TruScan RM devices enables you to seamlessly perform accurate chemical identification, while using your current TruScan RM Methods.

The Method Transfer data shown in this note provides confirmation that correct chemical identification will be achieved, whether a Method was created on a TruScan RM or TruScan G3 Handheld Raman Analyzer.

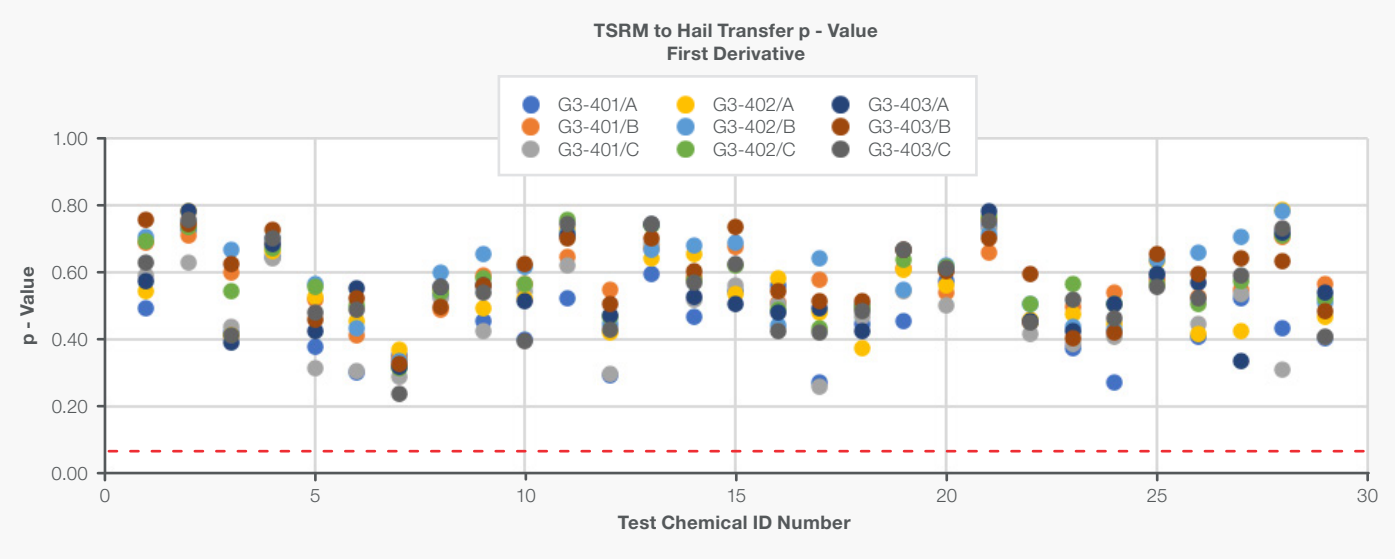

Figure 2. Method Transfer p-value results generated when assessing TruScan RM Methods transferred to TruScan G3 devices. Notation in legend refers to data acquisition on TruScan G3, using a Method created on a TruScan RM that was transferred to the TruScan G3 device. All chemical identifications passed with 100% efficacy across 9 combinations of Method Transfer. The red line at 0.05 indicates the pass/fail threshold for positive chemical identification for the p-value statistical method. This data set indicates that Method transferability from TruScan RM to TruScan G3 Handheld Analyzers provides the same chemical identification that users have come to rely on.

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