



HANDHELD ANALYZER FOR MATERIAL VERIFICATION AND IDENTIFICATION

The ASSURx instrument is a handheld Raman analyzer designed for material verification and identification in the warehouse, loading dock, lab or plant floor – wherever the material is located. The ASSURx analyzer verifies a material identity in 5-20 seconds, generates reports to satisfy regulatory compliance, and allows materials to flow quickly through the manufacturing process. Decrease your sampling and laboratory costs, and increase your inventory turns by incorporating an ASSURx Handheld Raman Analyzer into your pharmaceutical, nutraceutical, or cosmetic manufacturing process today.

RAMAN TECHNOLOGY ADVANTAGES VS. NIR

- + Raman has broader material coverage than NIR
- + Raman can analyze liquids and aqueous samples directly through packaging, whereas handheld NIR struggles
- + Raman is insensitive to particle size variations that can be found in powdered raw materials. In contrast, NIR has difficulty with different particle size distributions and requires averaging multiple measurements
- + Raman is insensitive to moisture variations. NIR is absorbed strongly by water, and can cause poor verification performance

ASSURX RAMAN ANALYZER ADVANTAGES

- + Fast measurements, fast library development, and high selectivity due to cooled, high-resolution spectrometer (5-20 second measurement times are typical)
- + Broad material coverage due to proprietary, advance fluorescencerejection algorithms, that allows for successful analysis of colored, and darker materials
- + Detection of samples with low Raman activity, like Bovine Gelatin, with actively cooled detector
- $+\ Affordable\ analyzer\ with\ full\ compliance\ and\ support$

ASSURX HANDHELD RAMAN ANALYZER KEY FEATURES

- + **Ergonomic, Gun-style,** point and shoot operation
- + Efficient workflows for both individual material scans, and high volume operations with large lots of materials
- + Individual and Lot Reports, with E-signatures

The gun-shaped ASSURx analyzer is both ergonomically-designed, and intuitive to operate. There are just 3 simple steps to conduct a material verification once logged in:

- 1) Use the barcode scanner to scan in the material to be analyzed.
- 2) Point the instrument so that it is in contact against a material's packaging.
- 3) Pull the trigger to initiate the analysis and see the Pass/Fail result on the screen.

For high-volume operations, the ASSURx analyzer auto-increments sample numbers, and generates Lot Reports so that batches of measurements can be easily conducted and summarized. With E-signing reports – it is easy for, supervisors to approve operator analyses.

- + **Fast material verifications:** 5-20 seconds typical
- + **Fast library development**, and easy library transferability between units
- + **Broad material coverage,** for organics, powders and liquids
- + **Proprietary data processing:** advanced fluorescence-rejection

The ASSURx analyzer's material verification mode is fast due to its cooled detector and its proprietary data processing. The same cooled detector and data processing engine also makes library entry and creation fast. With an industry leading 6 cm⁻¹, high resolution spectrograph, the ASSURx analyzer has high resolving power in the important Raman molecular 'fingerprint' region, allowing for high material specificity and broad chemical coverage. Having the sensitivity and resolution where it is needed in the Raman spectrum, ensures the best material verification accuracy.



+ **Direct, non-invasive, non-destructive analysis** through transparent/translucent packaging

For both solids and liquids in sealed transparent or translucent packaging, the ASSURx Handheld Raman Analyzer is the ideal material verification tool. It can analyze through glass and polymer bags with ease, whereas handheld NIR can be sensitive to some polymer packaging differences, and struggles with liquids in-situ.

- + Direct connection data transfer between unit and PC/network for easy data archiving
- + Meets regulatory compliance and requirements for: cGMP, 21 CFR Part 11, USP 1120, EP 2.2.48

All data collected on the ASSURx analyzer is encrypted, secure and audit trail tracked. Data on the ASSURx analyzer is read-only, and is permanently stored on a large 240GB hard drive. Data can be downloaded to PC or network storage location via a direct Ethernet connection or secure USB Flash Drive to archive reports and raw data.

The ASSURx analyzer meets the Raman instrumentation requirements stipulated in USP 1120 and EP 2.2.48. Being methodically calibrated at the factory, and functionally checked before shipment and at installation; TSI and TSI partners ensure ASSURx instruments are fully compliant with pharmaceutical manufacturers' regulatory needs.

- + **Swappable**, **rechargeable batteries** for continuous operation
- + Rugged design with shoulder strap

Designed for all-day, continuous use, the ASSURx analyzer comes with two batteries and a charging station so that while one battery is in use, the second battery can always be charging. Since the charging time of the battery is less than the use time of the battery, continuous operation of the ASSURx analyzer is possible. For operators using the ASSURx analyzer continuously, a comfortable shoulder strap is provided that allows the instrument to be easily carried around.



Specifications	
Method	Handheld Raman Spectrometer
Laser Wavelength	785 nm ± 0.5 nm, line width: < 0.15 nm
Laser Output Power	300 mW or below, adjustable on user-interface
Spectral Range	250-2350 cm ⁻¹
Spectral Resolution	~6 cm-1 (FWHM) across range
Detector Type	TEC temperature-controlled linear CCD array
Software	ASSURx-ID user-interface software for material verification, identification and library generation/management. ASSURx Reporter PC-software for report viewing, and file conversion to .spc and .txt file formats
Data Formats	.SPC, .TXT, .EPT (encrypted)
Report Formats	PDF with e-signatures
Connectivity	USB, Ethernet
Barcode Reader	Integrated. Compatible with most 1D linear barcodes (e.g. Code 39/32, Code 128, Code 93, and more)
Operating Temperature	0-40 °C
Display	Color touch screen; can be operated with gloves or integrated stylus
Battery	Swappable, rechargeable Li-ion, >3 hours operation, <2 hours charge (Continuous operation possible)
AC Adapter	DC Wall Adapter, 100/220VAC 50/60Hz
Compliance	US FDA 1040, 21 CFR Part 11 software – includes audit trails, administrator controls for logins, secure passwords with expirations, data encryption and integrity checks. USP Ch. 1120 EP Ch. 2.2.48
Dimensions (LxWxH)	9.21" x 4" x 8.77"
Weight	5.25 lbs.
Accessories - Included	Battery-charging stand, Spare battery, Vial Holder, Tablet Holder, 7 mm sampling lens, Ethernet Cable, Polystyrene PQ check standard, Acetaminophen, Acetyl Salicylic Acid check samples.
Accessories - Optional	Immersion probe
Warranty	One Year for Parts and Labor. Extended warranties are available.

FOR AN ON-SITE DEMONSTRATION, CONTACT A TSI® | CHEMLOGIX™ REPRESENTATIVE BY VISITING TSI.COM/ASSURX OR CALL 800-874-2811.



 $\textbf{TSI Incorporated} \cdot \textbf{Visit our website www.tsi.com} \ for \ more \ information.$

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