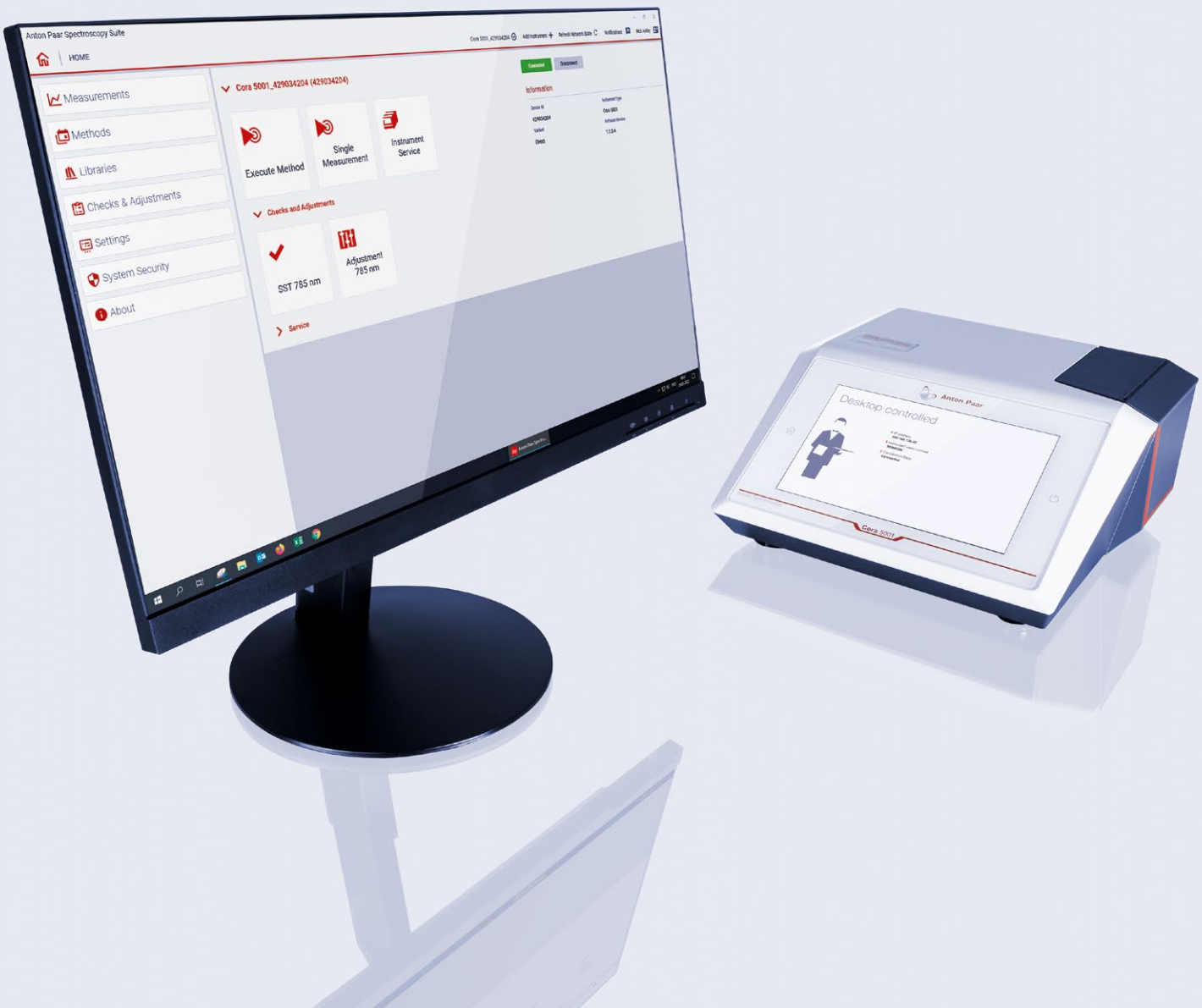
Efficiency Meets Compliance in Raman Analysis

Anton Paar

Cora 5001 with Spectroscopy Suite



Scan.
Match.
Result.

QUICK IDENTIFICATION AND VERIFICATION OF SUBSTANCES WITH Cora 5001 AND ANTON PAAR'S SPECTROSCOPY SUITE

Cora 5001, in combination with Anton Paar's Spectroscopy Suite software, is the solution tailored to incoming goods inspection and R&D in the regulated environment.

You need results, not spectra: The system takes all complicated spectroscopy aspects out of the daily measuring routines. Predefined workflows and settings, and autofocus and autoexposure speed up measurements and avoid errors before they can even occur.

All workflows, like running samples, setting up methods, and generating reference libraries, are specifically designed to adhere to stringent compliance regulations.

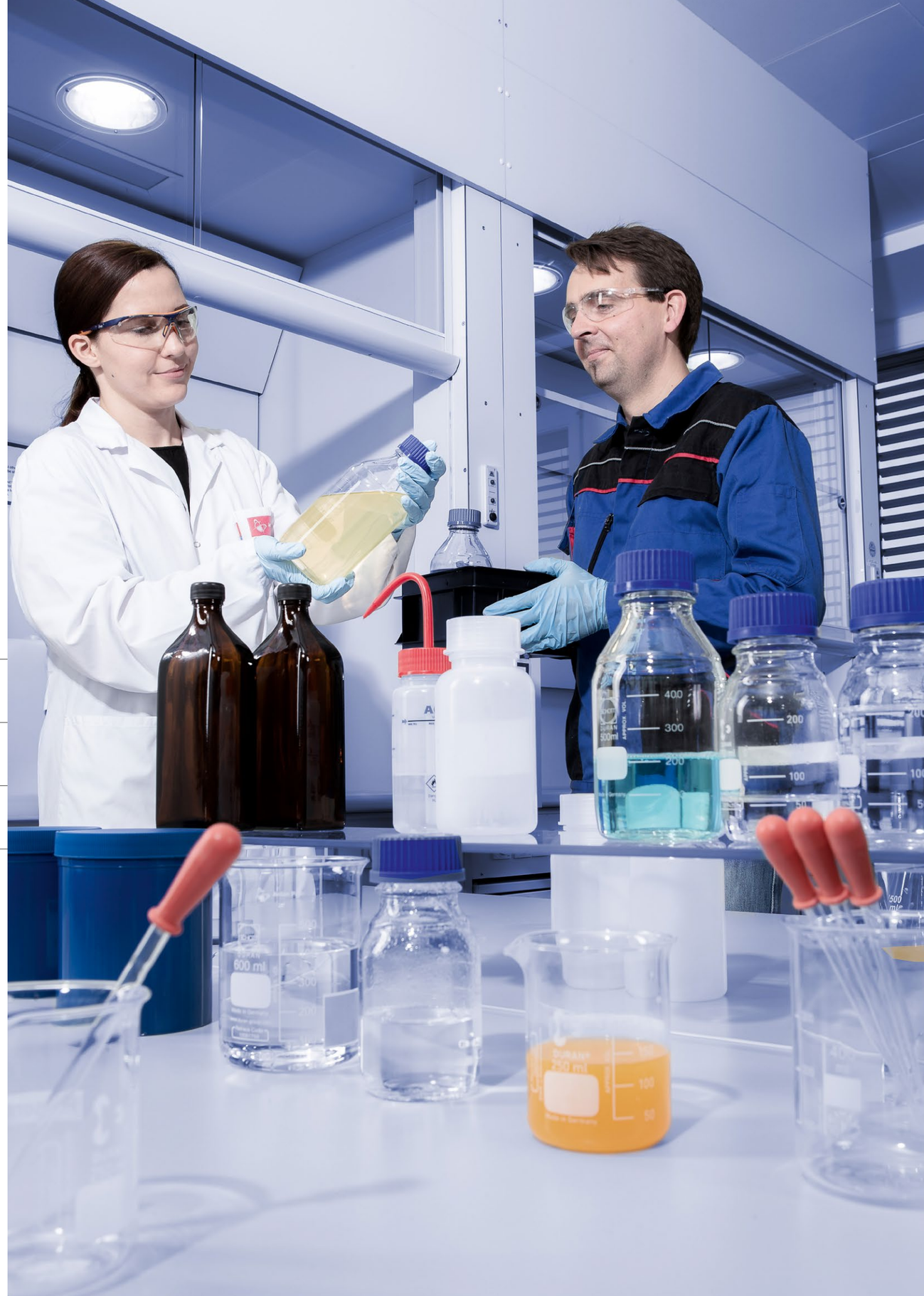
YOUR CHALLENGES

- ✓ I operate in the regulated environment and can never compromise on lifetime data integrity.
- ✓ I must always be able to demonstrate that the system adheres to 21 CFR Part 11 and EU GMP Annex 11.
- ✓ I need a system that avoids errors in the first place instead of making me chase them afterwards on the basis of audit trail entries.
- ✓ I need to check 100 % of the supplied goods, so no incorrect or contaminated raw materials are used in production, which could ruin the entire batch.
- ✓ It's my job to increase the efficiency of the QC laboratory, and I'm looking for a quick test to verify the chemical composition.

Cora 5001 WITH ANTON PAAR'S SPECTROSCOPY SUITE – THE SOLUTION TO YOUR NEEDS

FIND OUT MORE

www.anton-paar.com/apb-spectroscopy-suite



The Solution to Optimize QC

SIMPLE – FAST – AUDIT-PROOF

LIFETIME DATA INTEGRITY

100 % TRACEABLE AUDIT TRAIL WITH SEARCH FUNCTION

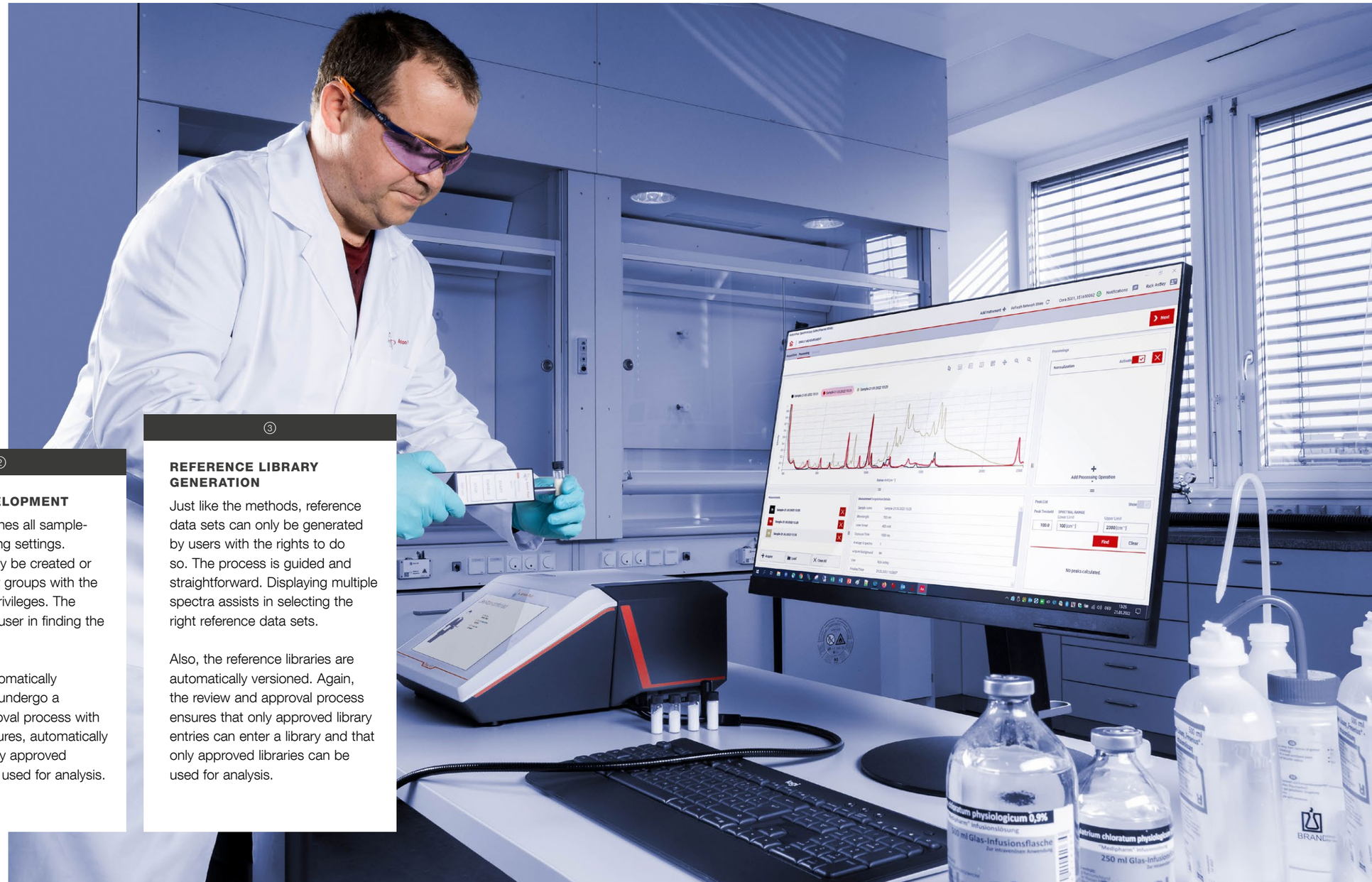
TRANSPARENT AND SECURE ELECTRONIC SIGNING

① Raman sample verification in seconds

② Expert tools for method development

③ Versioned reference library generation

→ **THE BEST MATCH OF HARDWARE AND SOFTWARE: TAKE OUT COMPLEXITY TO PERFORM IN THE REGULATED ENVIRONMENT**



①

SAMPLE VERIFICATION – THE DAILY ROUTINE

The day-to-day running of samples is safe and efficient: It can only follow clear and predefined methods. No measuring settings can be made. Autoexposure and autofocus ensure optimal conditions and eliminate human influence on results. The system automatically compares the measured spectra with the reference spectra library prescribed in the method and gives a pass/fail answer. A valid system suitability test is a prerequisite for starting a measurement.

Be sure no data sets are ever deleted, as these are securely stored in the SQL database. The electronic signing process ensures proper submission, review, and approval of data.

②

METHOD DEVELOPMENT

The method defines all sample-specific measuring settings. Methods can only be created or changed by user groups with the corresponding privileges. The system aids the user in finding the optimal settings.

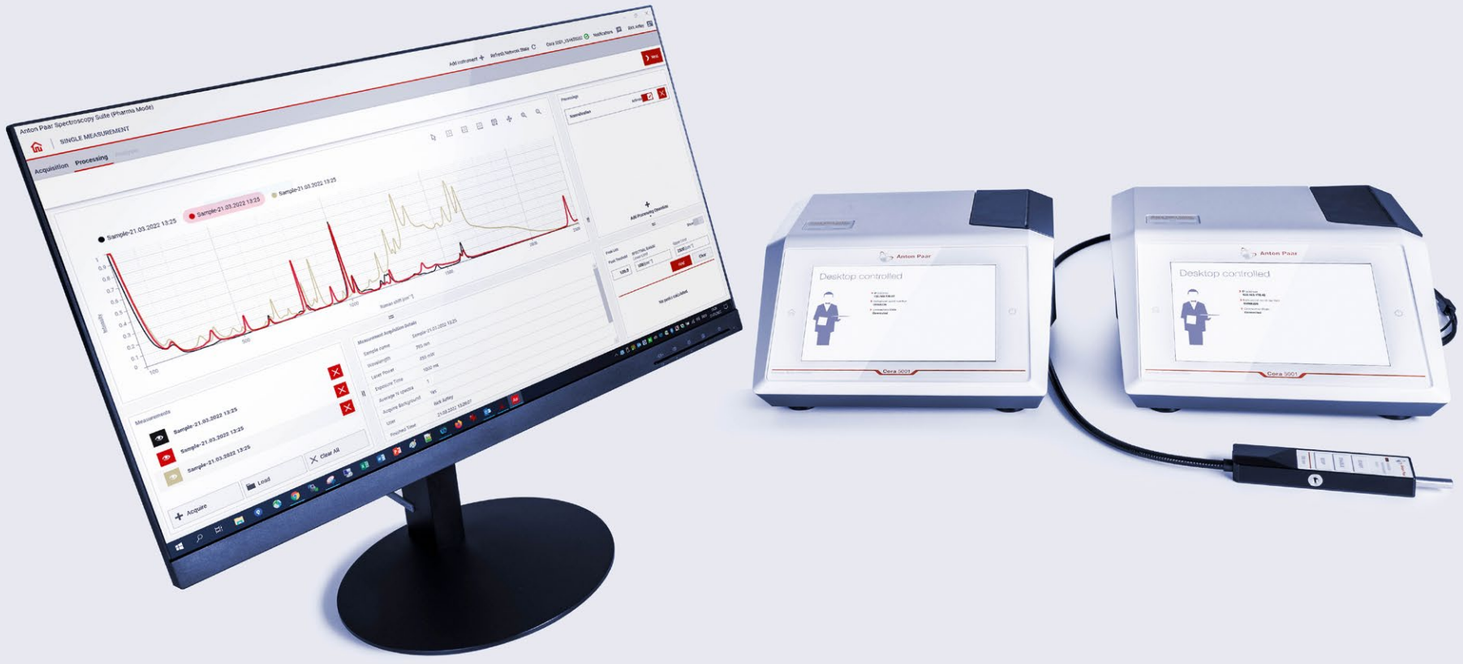
Methods are automatically versioned. They undergo a review and approval process with electronic signatures, automatically ensuring that only approved methods can be used for analysis.

③

REFERENCE LIBRARY GENERATION

Just like the methods, reference data sets can only be generated by users with the rights to do so. The process is guided and straightforward. Displaying multiple spectra assists in selecting the right reference data sets.

Also, the reference libraries are automatically versioned. Again, the review and approval process ensures that only approved library entries can enter a library and that only approved libraries can be used for analysis.



Avoiding Errors

THE SYSTEM'S RESPONSIBILITY, NOT THE USER'S JOB

ACCESS CONTROL ✓

- Choose from user management via active directory or locally managed user credentials
- Local user management provides:
  - Comprehensive password complexity settings
  - Password expiry dates
  - Auto logoff after a customizable idle time

USER GROUP ADMINISTRATION ✓

- User groups can be defined according to specific company standards
- Privileges can be defined specific to a user group

ELECTRONIC SIGNING PROCESS ✓

- Choose from a 2- or 3-step signing process depending on your company policies
- Signing of measuring results, newly created methods, and newly created library entries and libraries, as well as checks and adjustments

AUDIT TRAIL ✓

- Signing and commenting of audit trail entries
- Full-text search and filter functionality via data explorer

PHARMA QUALIFICATION PACKAGE* ✓

The Pharma Qualification Package (PQP) qualifies your instrument three times quicker. Enjoy a complete package of IQ/OQ/PQ, a risk analysis, and a 21 CFR Part 11 checklist.

** For Cora 5001 785 nm*

DATA MANAGEMENT ✓

- Full-text search and filter functionality via data explorer
- No deletion of data possible
- Lifetime data retention

TRACEABILITY AND DATA REPROCESSING ✓

- Versioned methods and libraries provide full traceability: For each measurement result, the version of method and library can clearly be traced back
- Reprocessing of original measuring data creates a new entry in the results database (no existing measurement result can be deleted or modified)

EXPORT, BACKUP, AND RESTORE ✓

- Backup and restore functionality
- Full SQL backup possible
- Export of results incl. spectra (.pdf/.png/.spc/.csv)

LIBRARIES ✓

- Factory library tailored to instrument's characteristics
- S.T. Japan library available with up to 16,000 spectra
- User-generated libraries specific to user samples

LIFETIME DATA INTEGRITY ENSURED FROM THE POINT OF INSTALLATION

Cora 5001 Series

MAKE YOUR CHOICE

SMALL AND EASY TO TRANSPORT

Cora 5001 is ready for use in the field, in your lab, and in the warehouse. If you need to analyze substances at their location, choose the battery option and measure on-site.

DISCOVER THE BENEFITS OF RAMAN TECHNOLOGY WITH Cora 5001

- ✓ Results within seconds – 300 times faster than alternative methods
- ✓ Non-invasive and non-destructive
- ✓ Save time: no sample preparation needed
- ✓ No influence of water on the results
- ✓ In situ, live reaction monitoring
- ✓ Safe measurement through packaging

Cora 5001 Direct

REPRODUCIBLE CONDITIONS FOR YOUR SAMPLE

Cora 5001 Direct analyzes samples in a closed measuring compartment. No sample preparation is required. Holders for tablets, vials, and more can be placed precisely onto the motorized sample stage.

LASER CLASS 1 FOR MAXIMUM USER SAFETY

The Cora 5001 Direct instruments are certified as laser Class 1. There is no need for laser safety measures – the instrument is as safe as a DVD player.

AUTOFOCUS – GETS THE STRONGEST SIGNAL

Manual focusing on thin or opaque samples with a weak Raman signal can be tricky. Cora's autofocus finds the spot with the best Raman signal within seconds.

Cora 5001 Fiber

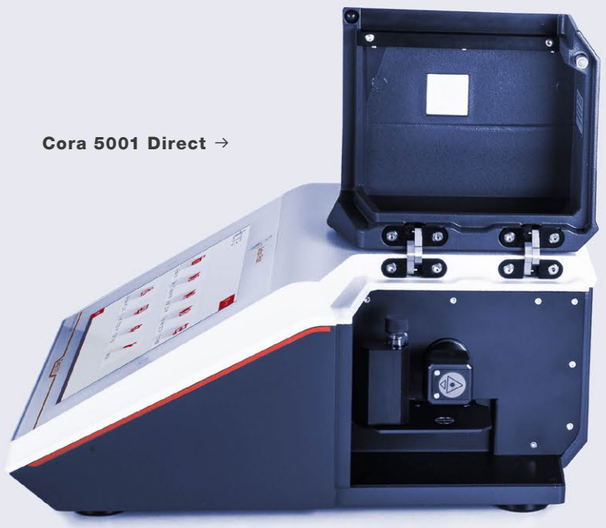
FLEXIBLE PROBE FOR MEASUREMENTS OUTSIDE THE INSTRUMENT

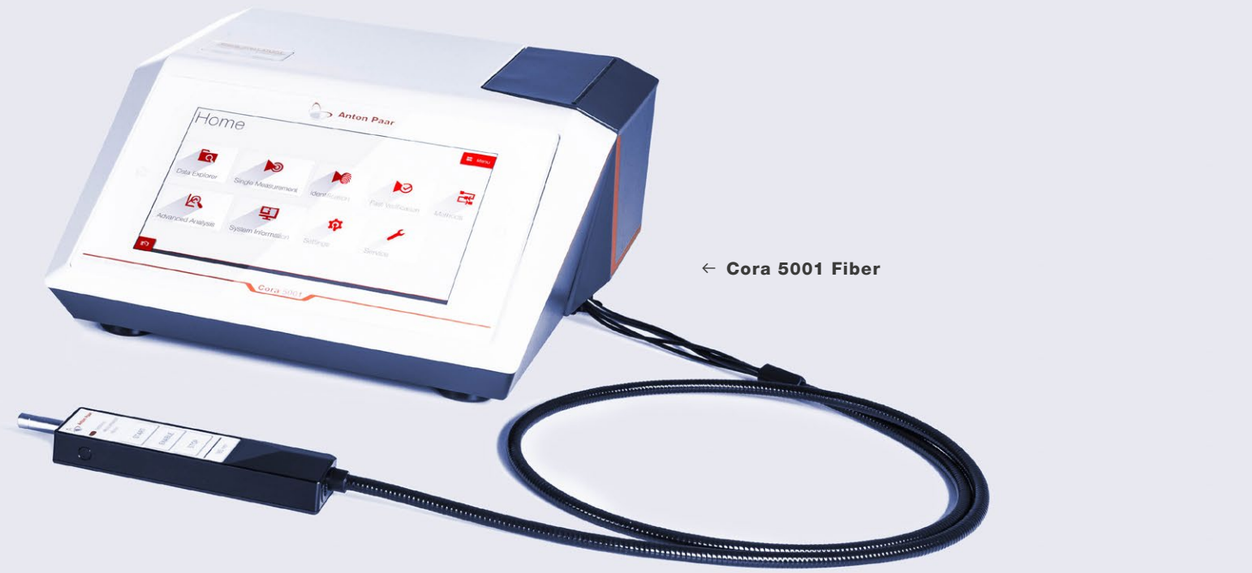
With Cora 5001 Fiber, the sample no longer needs to be taken to the instrument. You can analyze substances regardless of the sample's shape or size. The Fiber probe can even be used in situ.

SAFEGUARDED, ONE-HANDED MEASUREMENTS

Cora 5001's Fiber probes are the safe solution for one-handed measurements. Thanks to the remote trigger on the handle and redundant laser safety features, the user is securely in control of the process each and every second.

Cora 5001 Direct →





← Cora 5001 Fiber

Accessories for Efficient Work

WHATEVER SUBSTANCES YOU MEASURE, IN WHATEVER FORM, THESE ACCESSORIES ENABLE ANALYSIS IN JUST A FEW SECONDS

Cora 5001 Direct

USE YOUR OWN VIALS

We have the right holder for you – use your own round or rectangular vials or cuvettes of different sizes.

FOR PILLS OR OTHER SMALL SOLID SAMPLES

The pill holder positions small solid samples like pills and tablets.

FOR FOILS AND MICROSCOPE SLIDES

Thin samples like foils and slides can be inserted easily with the substrate holder.

ALL SAMPLE HOLDERS ARE EQUIPPED WITH MAGNETS THAT SNAP INTO PLACE PRECISELY AND ALLOW REPRODUCIBLE ANALYSIS WITHOUT REFOCUSING.

Cora 5001 Fiber

FIXED FOCUS ADJUSTMENT FOR YOUR FIBER

The docking station holds the Fiber probe and vials in place for reliable and reproducible results.

ACCURATE ADJUSTMENT AT THE TIP OF THE FIBER PROBE

If you need to analyze substances with a defined distance to the probe, use the adjustable spacer tip. This ensures consistent focusing and optimum signal acquisition.

THE ULTIMATE SOLUTION FOR ADDRESSING ANY SAMPLE

The xyz stage positions the Fiber probe precisely where needed. Micrometer screws for alignment in all three dimensions enable on-spot measurements even with samples of small size or a high level of inhomogeneity.

Anton Paar
Certified Service

“We’re confident in the high quality of our instruments. That’s why we provide **a full warranty for three years**.”

All new instruments* include repair for three years.
You avoid unforeseen costs and can always rely on your instrument.
Alongside the warranty, we offer a wide range of additional services and maintenance options.

*Due to the technology they use, some instruments require maintenance according to a maintenance schedule. Complying with the maintenance schedule is a prerequisite for the three-year warranty.

	Cora 5001
OPTICAL SPECIFICATIONS	
Excitation wavelength	785 nm
Spectral range	100 cm^{-1} to 2300 cm^{-1}
Resolution (according to ASTM E2529)	6 cm^{-1} to 9 cm^{-1}
Laser power	0 mW to 450 mW, adjustable
Spectrograph	f/2; Transmission Volume Phase Grating (VPG)
Integration time	0.005 s to 600 s
Wavelength calibration	Automatic via software
Detector array	2048 px CCD
Laser class	1 for Direct model; 3B for Fiber model
PHYSICAL SPECIFICATIONS	
Dimensions (D x W x H)	355 mm x 384 mm x 168 mm (14.0 in x 15.1 in x 6.6 in)
Weight	9.8 kg
Operating temperature range	10 °C to 35 °C (non-condensing)
Fiber probe dimensions	Cable length: 1.50 m
Battery (optional)	Lithium-ion
Battery run time	>1.5 h
Power supply input	Inline power supply input: 115/230 V AC, 50/60 Hz Car power adapter input: 9 V to 32 V DC
Power consumption	Inline power supply input: max. 100 VA
ADDITIONAL SPECIFICATIONS	
Display	10" touchscreen
Data ports	4 x USB 2.0, 1 x Ethernet, 1 x CAN out, and 1 x USB to PC
Data export formats	.csv, .txt, .png, .spc, .aps, .pdf
Internal storage	8 GB
Wireless connectivity	WiFi stick (optional)
Spectral libraries	Factory library, user-built, third-party options
Security	User roles with customizable permissions, user password logins

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