



• System Validation BRAVO

The development and manufacture of pharmaceutical products is subject to the strict rules of good laboratory practice. Bruker offers comprehensive system qualification that provides the documentation and procedures needed to use handheld RAMAN spectroscopy in compliance with the (c)GMP/GLP regulations.

A Validated Solution

- Fully automated OQ & PQ testing according to Ph.Eur., USP and JP requirements.
- Compliant to latest Data Integrity guidance by FDA.
- 21 CFR part 11 compliant electronic records and signature management.
- State of the art user management following the concept of segregation of duties (SOD).
- Comprehensive Audit Trails.
- System Validation Manual to support and document the qualification process.
- System qualification by certified service engineers.

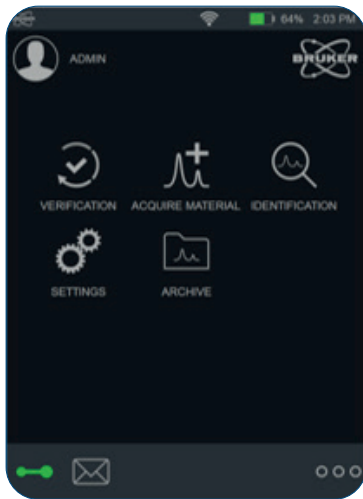
Concept

The handheld Raman spectrometer BRAVO shares the same meticulous validation concept as any other Bruker FT-IR/NIR or Raman spectrometer. The fully validated instrument software is flawlessly integrated to the validation concept of the OPUS spectroscopy suite to keep the cost of compliance at a minimum.

21 CFR Part 11 and beyond

365 degrees of compliance starts with software being dedicated to the Pharmaceutical industry, and which leaves no room for breach of regulations. The validation option for Bruker's software solutions sets all in place:

- State-of-the-art user and signature management, with advanced access control.
- Sophisticated user rights concept to ensure SOD.
- 4-Eye-Principle electronic signatures.
- The use of released methods and spectra as well as valid performance tests are enforced.
- Protected Data Pool for secure electronic records and software configuration.



BRAVO home screen with green status symbol indicating valid OQ and PQ tests.

OVP - Bravo PQ Protocol			
Company:	Bruker		
Operator:	Admin		
Instrument Type:	Bravo Handheld		
Optics Configuration:	Channel with: Lasers C-H & Fingerprint, Grating, Detector		
Accessory:	None		
Instrument Serial Number:	BRV02005		
OPUS/DB Version:	2.0 Build: 2.0.12.141 / 34.8.3		
OPUS/DB Version:	OPUS 8.2 Build: 8.2.28 / DB: 8.7.0.12		
Overall Test Result:	PASSED		
Test expires:	14.12.2019, 16:26:36 (GMT+1)		
Test Date/Time:	13.12.2019, 16:26:36 (GMT+1)		
Test Spectra Path:	C:\Users\Public\Documents\Bruker\OPUS_8.2.28\Validation\Data\20191213162636		
Date of last PQ Reference Measurement:	22.07.2019 10:36:15		
Comment:			
Wavelength Accuracy Test - Polystyrene Vial			
Ref. Peak (cm-1)	Allowed Dev. (cm-1)	Meas. Peak (cm-1)	Meas. Dev. (cm-1)
620.90	2.50	621.01	0.11

Automatically generated non-editable instrument qualification protocol.

Performance Qualification – USP <858> & <1858>, Ph.Eur. 2.2.48

With BRAVO Bruker challenges current regulations setting a new benchmark for handheld Raman instruments being operated in the Pharmaceutical industry. Chapters Ph.Eur. 2.2.48 and USP <858> of the European and United States Pharmacopeia define minimum performance specifications for Raman instrumentation, respectively. Chapter 2.2.48 of the European Pharmacopeia 8.7 for the first time did consider specifically handheld Raman analyzers, and as well USP did introduce with chapter <858> explicit acceptance limits for wavenumber accuracy.

The optics of BRAVO have been designed to achieve highest standards in accuracy, being even capable to match the tighter performance limits set for benchtop equipment (P.Eur.), or quantitative analysis (USP). Routine Performance Qualification via the OPUS Validation Program OVP considers all individual requirements set by Pharmaceutical regulations, complemented by additional test procedures.

Data Integrity

Data integrity is a very important aspect especially as nowadays electronic records are getting established. OPUS and BRAVO strictly follow the ALCOA plus principle, considering all attributes which valid data needs to comply to.

Electronic records generated on a mobile device are highly sensitive, as this implies that the requirement for secure electronic records being contemporaneously recorded is not fulfilled by default. With BRAVO's Sync Service it is assured that electronic records on device are transferred at first occasion to the Protected Data Pool – the OPUS solution for secure electronic records.

Ready to Use System Qualification

The manifold aspects of instrument qualification is offered for BRAVO as a single package, ready to use upon installation, with minimum efforts upfront. The System Validation and Qualification Package (S011) comprises

- Validation package for (c)GMP/GLP compliance of OPUS and BRAVO considering 21 CFR Part 11 (electronic signatures/records) and Data Integrity aspects, along with a dedicated user management.
- Certified reference materials according to ASTM E1840, USP <858> & <1858> and Ph.Eur. 2.2.48 for comprehensive performance testing. Polystyrene reference certified traceable to NIST 1921b.
- System Validation Manual

Validation Options

- S011** is the comprehensive carefree package.
- S010/BRAVO** System validation manual and electronic version S010/BRAVO-E.
- O/VAL** Software package to run OPUS and BRAVO in validation mode.
- BRMxxx** Certified reference materials.
- S020-MR** Validation service incl. IQ/OQ/PQ performed by a certified service engineer.
- S9xxx** Maintenance and Service contracts incl. revalidation

System Validation Manual

The Bruker System Validation Manual forms the profound base of instrument qualification. It covers all regulatory requirements from Design (DQ), Installation (IQ), Operational (OQ) to Performance Qualification (PQ).

The document furthermore includes

- Software release documentation and certification.
 - Compliance certificates
 - Ready to use log forms to document and guide step-by-step the instrument qualification.
- and many more.

Bruker Optics is ISO 9001 and ISO 13485 certified.

Laser class 1 product.

Technologies used are protected by one or more of the following patents:
US 7034944; DE 19940981

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