



• 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.

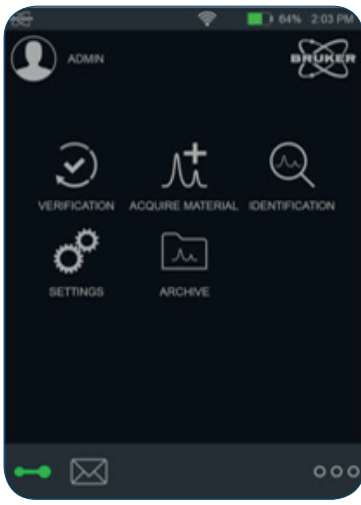
Concept

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:	BRV00065		
Instrument Firmware 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 <1120>, Ph.Eur. 2.248 and beyond

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 <1120> of the European and United States Pharmacopeia define minimum system specifications for Raman instrumentation, respectively. The recently revised chapter 2.2.48 of the European Pharmacopeia 8.7 for the first time considers specifically handheld Raman analyzers, but in a way that the requirement for the Raman shift accuracy is softened compared to conventional benchtop spectrometers. A move in contrast to the capabilities of modern instrumentation, which is as well projected to be harmonized in next USP revisions.

The optics of BRAVO has been designed to achieve highest standards in accuracy, which typically allows matching the specifications applicable for benchtop instruments.

Anytime, the performance of the system can be automatically challenged with comprehensive system tests according to current regulations making data and test reports available for documentation.

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.

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

www.bruker.com/optics ● Bruker Scientific LLC

Billerica, MA · USA
Phone +1 (978) 439-9899
Fax +1 (978) 663-9177
info.bopt.us@bruker.com

Bruker Optik GmbH

Ettlingen · Germany
Phone +49 (7243) 504-2000
Fax +49 (7243) 504-2050
info.bopt.de@bruker.com

Bruker Shanghai Ltd.

Shanghai · China
Phone +86 21 51720-800
Fax +86 21 51720-899
info.bopt.cn@bruker.com

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.