

Product Note R35 - 12/19

## BRAVO – The must have handheld Raman solution for Pharmaceutical Industry

### Advantages

- SSE™ - Patented fluorescence mitigation
- DuoLaser™ - Large spectral range
- Laser class 1 - safe operation
- Intuitive and guided touchscreen operation
- Highest wavelength accuracy and precision
- Enhanced material distinction
- Compliant to latest Pharma regulations

Process and cost optimizations challenge our daily business. By introducing handheld Raman spectrometers that enable to probe materials like active pharmaceutical ingredients or excipients directly through transparent packaging at any location new opportunities emerged.

With BRAVO the dedicated handheld Raman solution for the Pharmaceutical industry combining outstanding performance and ease of use, Bruker started a new era in material control.

### SSE™ – Patented Fluorescence Mitigation

Sequentially Shifted Excitation allows measuring more materials compared to conventional handheld Raman spectrometers by mitigation of fluorescence while keeping the performance at least as high as for benchtop systems (Figure 1).

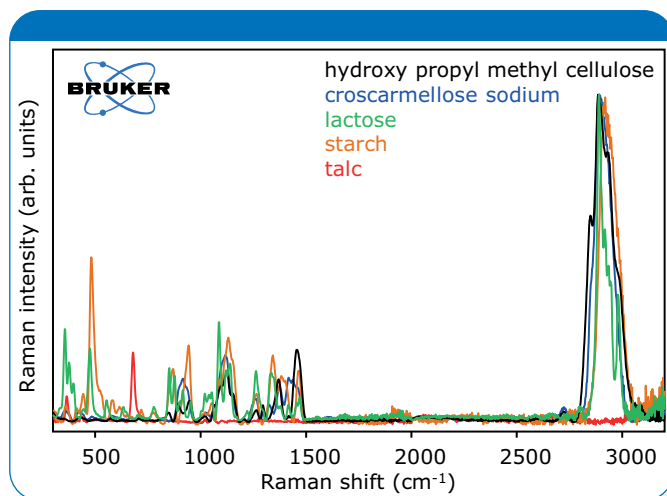
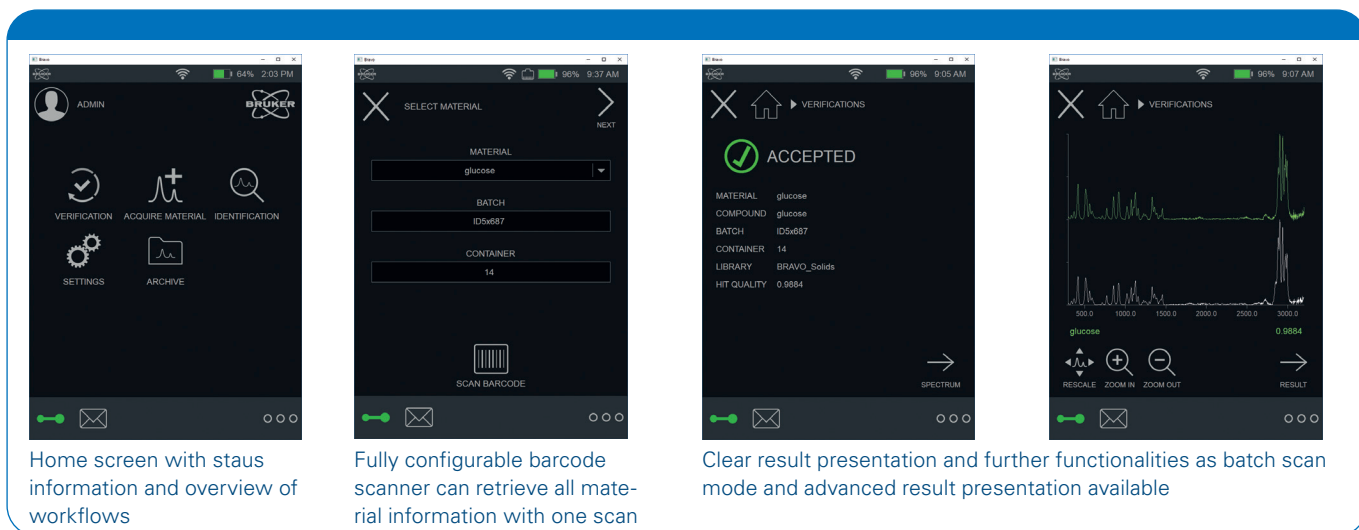


Figure 1: BRAVO SSE™ spectra of typical Pharmaceutical excipients.

### Duo LASER™ Excitation – Large Spectral Range

BRAVO allows recording a large spectral range from 300  $\text{cm}^{-1}$  to 3200  $\text{cm}^{-1}$  Raman shift and hence provides even information from the CH-stretching range (Figure 1).



Home screen with status information and overview of workflows

Fully configurable barcode scanner can retrieve all material information with one scan

Clear result presentation and further functionalities as batch scan mode and advanced result presentation available

Figure 2: Verification workflow

### Intuitive and Guided Touch screen Operation

Likewise the operation of a smartphone the user is guided through a clearly laid out user interface designed for the needs of material inspection. BRAVO provides highest standards and sophisticated workflows for an efficient operation (Figure 2).

### Material, Method and Library Setup

BRAVO makes building libraries quick and easy by an intuitive workflow in combination with Bruker's powerful OPUS software suite. Due to the high precision optics of BRAVO best results in the market using an HQI approach are achieved enhancing the distinction of even very similar materials. In Table 1 results from the verification of celluloses are presented comparing an HQI approach and an HQL approach in combination with SSE™. It can be clearly seen that an

HQI approach with BRAVO already results in a successful distinction which can be significantly increased further by combination with SSE™.

### IntelliTip™ - Automated Tip Recognition

When acquiring library spectra BRAVO stores tip information automatically and advises during the verification process which tip to be used. IntelliTip™ hence always ensures that the proper tip according to the material to be measured is applied in order to receive best spectrum quality at any time.

### Validation

BRAVO and all of its software are fully compliant to the latest Pharmaceutical regulations like 21 CFR Part 11, PhEur 2.2.48 as well as USP 1120 and considers the concept of Data Integrity according to latest FDA guidance. Due to the robust and precise optics BRAVO's wavelength precision and accuracy by far exceed the recently specified regulatory requirements for handheld Raman spectrometers and outperforms those of other handheld Raman devices. In particular it can be noted that BRAVO's performance is comparable to high performance benchtop Raman spectrometers and matches even the more stringent regulatory requirements of this instrument class. Reference standards for comprehensive system tests of BRAVO are according to ASTM 1840 as specified by the USP and EP regulations and of course a comprehensive validation manual including certificates and step by step instructions for IQ, OQ and PQ procedures is available.

Sample evaluated towards MCC	Correlation (no SSE™)	with SSE™
microcrystalline cellulose (MCC)	1	0.99
Hydroxy propyl methyl cellulose (HPMC)	0.93	0.58
Hydroxy propyl cellulose (HPC)	0.86	0.87
Sodium carboxy methyl cellulose (SCMC)	0.97	0.66

Table 1: Spectra of different cellulose materials tested against a method for the verification for MCC. The calculated correlation is displayed with and without the use of the SSE method.