



## B.I.-Methods 2.0

- Enabling Standardization of IVDr by NMR (for research use only)

Clinical and translational research by NMR is rapidly growing and worldwide networks of research groups such as the Phenome Center Network are forming. As a result, there is an increasing focus on standardization to maintain the transferability and reproducibility of the data.

Currently there is an emphasis to standardize the following:

- NMR instrumentation
- Standard operation procedures
- Analysis procedures
- Metadata handling

Now available on the AVANCE™ IVDr system, B.I.-Methods is the basis for data analysis technology developments and enables standardization of body fluid analysis by NMR.

B.I.-Methods link the IVDr platform with Bruker's automatic data analysis service and contains all automation methods needed for standardized data generation of body fluids. It also includes efficient quality control methods needed when working on human samples and ensures transferability of spectral data generated. While the entire system is for research use only, B.I.-Methods paves the way for possible future use in clinical settings by fulfilling certain requirements for accreditation and certification.

The methods and solutions described here are for research use only and not for use in clinical diagnostic procedures.

## B.I.-Methods 2.0 Includes

- Standard operating procedures for body fluids sample preparation (urine, plasma/serum, CSF and Methanol extract of body fluids, cell cultures and tissues)
- Standardized parameter sets for body fluids and quality control measurements
- Quality control reporting system including validation reports and control charts
- QuantRefManager fully integrated in TopSpin™ to manage quantitative calibration of the IVDr system for all body fluids
- Automatic configuration of IconNMR according to the requirements of the IVDr system
- Standardized templates for SampleTrack
- Module for automatic access to Bruker Data Analysis Server
- IVDr Data Browser allows an easy management of the IVDr data (spectra and metadata) and enables to select, copy or overlay a part of them

## Benefits of B.I.-Methods 2.0

- Standardized data generation and high data quality obtained in full automation
- Stringent spectrometer calibration and QC validation including stringent reporting
- Enabling sharing and co-development of statistical models across laboratories
- Reliable and consistent NMR data generation in large scale studies with long term horizons
- Supporting NMR laboratory network approach including phenome center networks

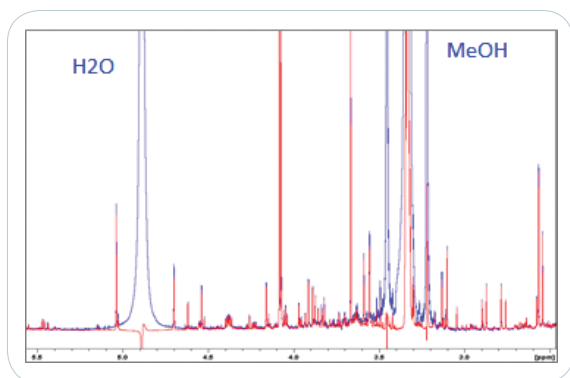


Figure 1: Performance of fully automated 4-fold solvent suppression in urine extract.

	Urine	Plasma / Serum	CSF	Methanol Extract
O1 optimization experiment	✓	✓	✓	✓
Preparation experiment 1				✓
Preparation experiment 2				✓
1D NOESY Presat	✓	✓	✓	✓
CPMG		✓		
Diffusion Filter		✓		
Fast 2D JRES	✓	✓	✓	✓
QuantRef calibration	✓	✓	✓	✓
Tube operation 3 mm & 5 mm	✓	✓	✓	✓

Table 1: Overview of body fluid NMR related parameter sets of B.I.-Methods 2.0

	Tube Diameter	QC Report	Control Charts
Filcor calibration	5mm	✓	✓
Temperature calibration	3 mm & 5 mm	✓	✓
Shim & water suppression optimization	3 mm & 5 mm	✓	✓
QuantRef calibration & validation	3 mm & 5 mm	✓	✓
Body fluid NMR SOP validation	3 mm & 5 mm	✓	✓

Table 2: Overview of calibration and quality control (QC) methods, reporting and control charts included in B.I.-Methods 2.0.

## Purchasing the B.I.-Methods Package 2.0

The B.I.Methods 2.0 package comes standard with the AVANCE IVDr platform. It can also be ordered to upgrade suitable non-IVDr systems to IVDr or IVDr compatible systems (Avance III HD or Avance Neo). Installation of the B.I.Methods 2.0 module is done by specially trained service engineers as part of the IVDr set up or as upgrade to non-IVDr systems. This ensure the B.I.Methods 2.0 package is correctly installed and the instrument is properly calibrated and connected to Bruker Data Analysis Server.