analytikjena

Technical data

Software WinASPECT®

Software for PC control of the SPECORD® and SPEKOL® product family

General

- Software for controlling the device and for evaluation of data (OS: Windows XP Professional or higher)
- Clearly arranged user interface and user direction
- Online-readout
- Modules available: Quant, Kinetics, Bio, Methods (for integration of customer-specific programmed macros), data handling, water analysis, 21 CFR Pt 11 compliance
- Link to AJAQC or other LIMS-systems
- User-specific export of data to external programs (e.g. Excel)
- Accessory-associated methods (e.g. determination of DNA-melting points with Peltier-thermostatted cell holder/changer)
- Control of relevant device parameters with service check programme* (comparance of beam energy/baseline/lamp check/wavelength correction) *valid for SPECORD$^®$ only

Module Quant

- Quant> Lab: determination of concentration by factor or calibration curve, various calibration models, measurement of check samples, statistical functions
- Quant> Routine: calibration and sample measurement in one step

  - Determination of concentration by factor or calibration curve (3 regression models)
  - Storage of methods (including sample table, measuring parameters and calibration)
  - Configuration of multiple batches
  - User-defined configuration of reports by user
  - Automatical save of raw and measuring data and export respectively
- Activation/Deactivation of standards and samples

Module Kinetics

- Linear Kinetics, statistical function

Module Bio

- Quantification of nucleic acids and proteins using pre-programmed methods (e.g. A260, A280, A260/280, Warburg Christian formula, Scopes formula and many more)
- Input and storage of user-defined formulae, various mathematical operations for up to 10 wavelengths

Module data handling

- Addition and subtraction of spectra, smooth function, calculation of derivative spectra, standardization, automatical or interactive peak search function

Module water analysis

- Various pre-programmed calibrations for MERCK water analysis kits

Module 21 CFR Pt 11 Compliance

- User management including 4 user levels plus administrator function, electronical signatures

Quality control

- QC-Module for quality control (QC-sample, QC-standard, QC-blank)
- Reaction on exeeding of defined error limits possible
- User specific definition (pre-period, control period) of quality control (recovery , mean and standardized mean card)
- Survey of limits of detection and of quantitation

Protocol

- Customer-specific configuration of report
- Complete documentation of data by means of the „Audit trail" function
  - <u>WinASPECT validation software for SPECORD®:</u>
    - o Verification of all relevant device parameters according to the guidelines of the Pharmacopeia Europaea