

UVS 3 / UVS X 3 21 CFR Part 11

Spectrophotometry Data System for UV/Vis Spectrophotometer

- ✓ Software for instrument control and data acquisition with SQL database for direct storage of methods, raw data and the complete process trail.
- ✓ MS SQL Server Always On high-availability clustering compatible
- ✓ Full GLP compliance due to clear database structure for method revision, raw data, calculation and report already with the basic version UVS 3
- ✓ Method generation for the definition of measuring conditions and complete result calculation
- ✓ UVS X 3 MasterMethods add-on to ensure fulfillment of method approval processes at anytime
- ✓ Full flexibility* allowing to switch between development and production tasks in qualified environments, independently of the photometric system itself *requires the MasterMethods add-on
- ✓ Powerful integrated formulae editor allows automated calculation of complex relationships over several samples or different wavelengths, including self-defined variables
- ✓ Integrated Report-Manager for free definition of content and layout of reports
- ✓ Automated electronic export of reports in self-defined formats, API for connection to LIMS- and ELN-systems or for paperless documentation
- ✓ Add-on for MS SQL Server Always Encrypted data protection will be available
- ✓ Version 3 for Specord® and Uvikon XS/XL spectrophotometer, validated with Windows 10
- ✓ USB Dongle as software protection for UVS 3 and UVS X 3



Covering all requirements in UV/VIS Spectrophotometry

The UVS software supports practically all applications in Spectrophotometry with a significant improvement in efficiency. Ranging from simple absorbance measurement at a single wavelength or complex calculations based on multiple wavelengths, wavelength scans with calculations based on extracted data up to reaction calculations for parallel measured samples for kinetics - all methods are available at your fingertips.

- Measurements at a single wavelength, also with calibration curve
- Measurements at multiple wavelengths with calculations over several wavelengths
- Wavelength scans with the possibility to define calculations based on values directly from a scan.
- Kinetics (measured sequentially for fast kinetics or in parallel with up to 10 samples for slower reactions)
- Multi-wavelength kinetics for up to 10 / 14 samples

Full 21 CFR Part 11 compliant edition available

For the rigid requirements of the FDA in the pharmaceutical environment a 21 CFR Part 11 compliant edition of the UVS software is available. This UVS X 3 edition includes the following additional functions:

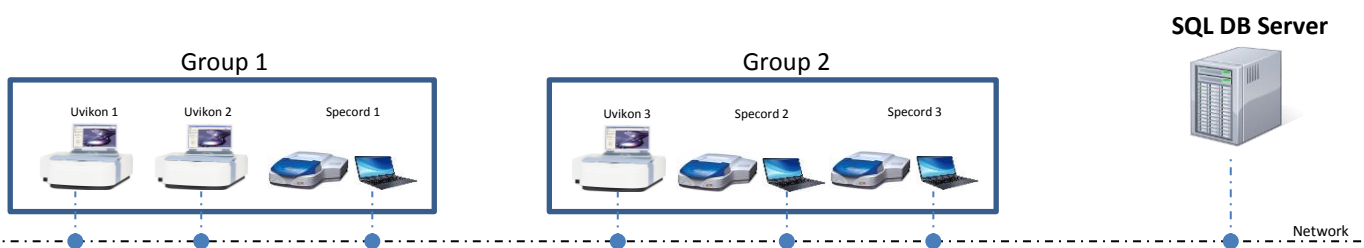
- Fully integrated User Management with login and password check as well as individual access limitations to the software functions - the administrator can e.g. restrict method creation and modification to a limited number of users
- Complete Audit Trail
Any action is automatically recorded in the audit trail indicating the detailed description of the action, the user name and date / time / time zone
- Electronic Signature
According to the FDA guidelines, electronic records and reports can be signed with login name & password - thus avoiding paper documentation

Based on a SQL database with true client/server architecture

Already the basic edition UVS 3 stores all raw data, methods and calculations directly in a SQL database, thus achieving full data integrity. A professional SQL database offers maximum data security and data integrity – users have no possibility to manipulate the contents of the database nor to delete any part. The strict regulations of the FDA's 21 CFR Part 11 are thereby fully met.

Pools of photometric systems are configured with a central SQL database (see figure below). Compatibility with Microsoft SQL Server Always On high-availability clustering is provided.

Stand-alone photometric systems can be implemented with a local or with a remote SQL database.



Workgroup & Datagroup features for access control

Workgroups can be defined to allow system filtration within the database: When starting UVS 3, the user will only be granted access to the systems belonging to the same Workgroup(s) as the system he is currently using.

Datagroups can now be defined within *Workgroups* to allow data filtration within the database (21CFR Part 11 edition only): When login into UVS X 3, the user will only be granted access to the Reports and to the Methods belonging to the same Datagroup(s) as he is part of.

Data backup and archiving

Implementing a SQL database does not only ensure full data integrity but also allows for establishing an automated database backup by the use of the corresponding database tools. Long-term archiving can thereby also be achieved.

Data integrity and traceability

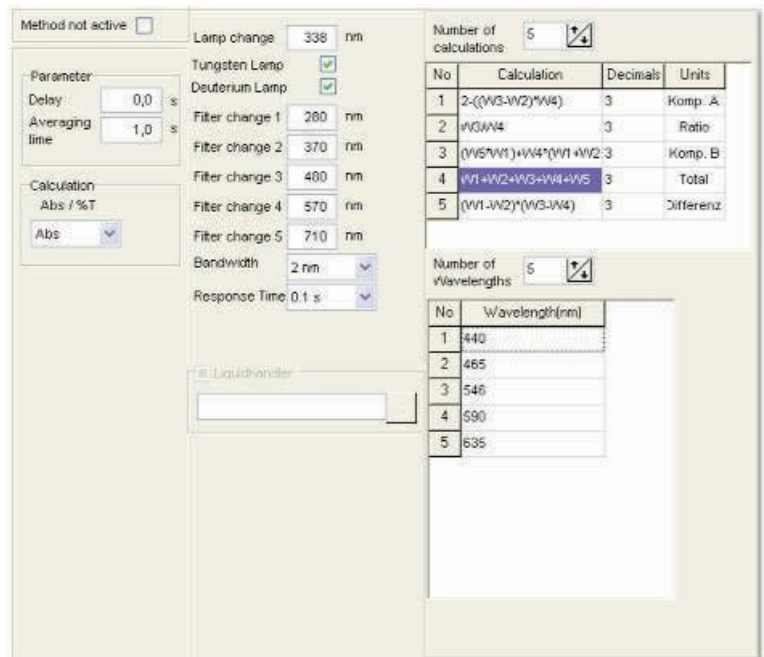
Data integrity is achieved by requiring the definition of a name for each measurement even before the data acquisition starts. Each dataset and each dataset modification is thereby unerasably stored in the database even before the data is displayed.

Each action, even the abortion of a data acquisition, is unerasably linked to the dataset in the audit trail and stored in the database. For each action the audit trail logs *who – when – why – which parameter was modified – from which previous value – to which new value*.

Simple method generation

All measuring conditions for executing the experiment as well as the formulae for calculating the result of a specific application are defined in a method stored in the database. Raw data and calculated results can be clearly traced due to an automatic link to the method.

If, in the 21 CFR Part 11 compliant edition, a method is modified by authorized personnel it is stored as a new revision. The previous version can be marked as "inactive" and can no longer be used for further data acquisition.



Complex calculations fully automated

The integrated powerful formulae editor allows automation of any calculation in a very simple way. For calculations over several measurements or samples, e.g. for highlighting an intermediate step of a reaction, or for calculating the result based on multi-wavelength measurements; the formulae editor can define the calculation in the method and thereby fully automate the final result calculation.

Thus the risk of errors while transferring data to another calculation program are completely eliminated and consequently time-consuming validation becomes unnecessary.

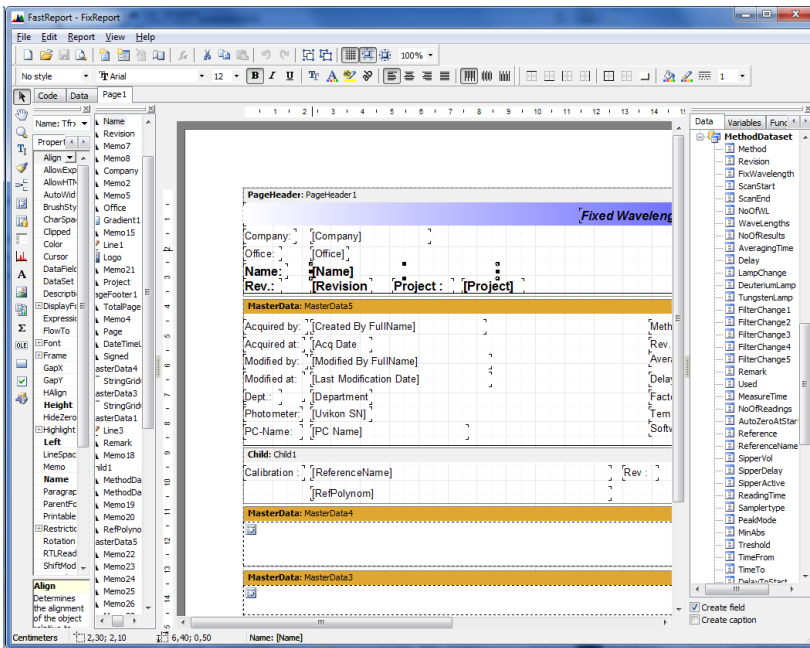
MasterMethods feature add-on and total task flexibility

Photometric systems had to be previously dedicated to method development/validation or to productive measurement purposes.

Now with the UVS X 3 photometer data system and the MasterMethods add-on, it is not only possible to roll-out approved methods from a validation system to the productive photometric pool of systems but also to overcome tasks restrictions. Validation and production activities are now completely flexible:

Each system can act as both a validation and also a measuring platform, while both tasks are completely kept separate. This is even possible on a stand-alone UVS X 3 system with a single local database.

Professional Report Layout



The integrated Report-Manager allows to define the contents and the layout of a report that is stored as a report template. Free text can be combined with system variables and graphics and also the order of columns in the result tables can be rearranged. Every element format can be individually defined in terms of font, color and size.

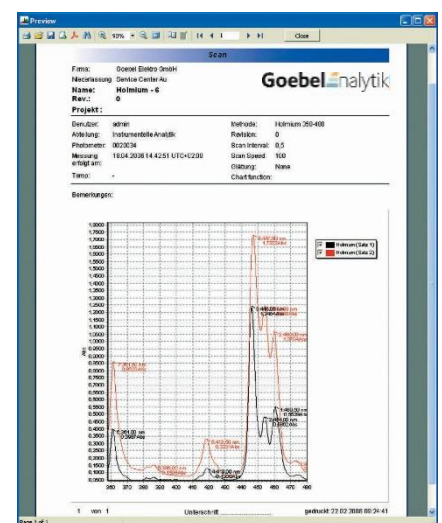
Thus, specific report forms can be directly created, eliminating the need to transfer data to any other program for layout design.

Integrated Workflow Management

Once measuring parameters and all calculation formulae have been saved in the method and this method is set to status "active", to start the measurement you only need to select the required method, number of samples and any initial blank runs. The correct setting of all measuring conditions, changing to further samples when using an automatic cell changer or liquid handler, storage of raw data, calculation of results and reports and even the report printout are generated completely automated.

In the 21 CFR Part 11 compliant UVS X 3, the data export can be linked to a specific electronic signature, if needed. Data and results can be exported in multiple formats (e.g. Excel and PDF).

In case of long-term studies, additional samples can be added to a dataset at any given time by reloading a dataset.



LIMS and ELN interfacing add-on

The UVS X 3 photometer data system can not only be interfaced with electronic data management solutions but even remotely controlled from a distant LIMS user-workstation. Both reports and raw data can be automatically transmitted. Currently SOAP protocol support is provided ; REST support will follow soon.

Ordering information

78-30201

UVS 3 data system for Specord® or Uvikon incl. USB Dongle

78-30200

*UVS X 3 data system for Specord® or Uvikon incl. USB Dongle
fully 21 CFR Part 11 compliant*

78-302MM

UVS X 3 MasterMethods add-on

78-30207

UVS X 3 LIMS/ELN add-on

Goebel Instrumentelle Analytik GmbH

Mainburger Str. 8
D-84072 Au i.d. Hallertau
Deutschland

Tel.: +49 / (0) 87 52 / 86 708 - 0
Fax: +49 / (0) 87 52 / 86 708 - 20

WEB: www.goebel-analytik.de
E-Mail: analytik@goebel-analytik.de