

## UVSX 21CFR Part 11 Compliant Software for UVIKON XS / XL

### Overview

The UVSX 21CFR Part 11 compliant software is available as an option for the UVIKON XS and XL spectrophotometers.

The software supports all common UV/VIS methods including both multiple activity calculations within a run and multi-wavelength kinetic capabilities using an automatic cell changer.

The possibility to include control of external autosamplers for fully automated analysis of large batches of samples is also available and can be configured to suit the type of sampler and customer requirements.

#### High Security Level

Only Administrators have access to the security settings for Options, Backup and Login. The software automatically checks for serial number and instrument type at every start-up. Group definitions allow data to be filtered for display according to the logged-on users.

#### Fully compliant with 21CFR Part 11 Rules

Access rights and user permissions are defined by the administrator in a controlled security area. Methods and acquisition reports are maintained under strict revision control. Configurable audit trail for complete history tracing including a deleted report trail. A statement covering all aspects of the compliance with the requirements of 21CFR Part 11 is available by following the documentation link above.

#### Electronic Signature

Reports can be formally signed with an electronic signature provided appropriate rights have been assigned. Once signed the report is frozen and cannot be modified as required under 21CFR Part 11 rules. All signed reports carry appropriate labels on any printed documents for easy identification.

#### Lite Version

A Lite version of the software is also available for users who do not require compliance with 21CFR Part 11. This software has the same basic functions as the UVSX software but without the extra user administration and audit trails.

#### Uvikon 900 Upgrades

A special upgrade package is also available for the Uvikon 900 spectrophotometer in order to allow the UVSX software to be used. This upgrade covers both hardware - new processor board and hard disc - and the UVSX software.



### Specifications

Available Methods	
Fixed Wavelength	Data in AU, %T or concentration with factor
Wavelength Program	Data acquisition at between 2 and 14 wavelengths at high slew speeds.
Wavelength Scan	Acquisition of spectra
Time Drive	Acquisition of kinetic data over user-defined time intervals
Auto Rate Assay	Acquisition of kinetic data for multiple samples using a cell changer, measurements within the same run but at different wavelengths are also supported.

Calculation modes	Enzyme activities with regression, calibration, curve factors, derivatives, wavelength ratio, wavelength differences, blank subtraction
<b>Other Functions</b>	
Cursor	Selectable cursor for curves with real-time display of co-ordinate values
Zoom	Zooming permanently active in curve displays via mouse
Peak detection	Peak detection for peaks, valley or both, selectable threshold and sensitivity
<b>Security Functions</b>	
System access	Only users with administrator rights can access the system security settings for defining users etc.
User access	Password and User Name are required to log onto the system. Individual user rights must be first defined by the administrator
Groups	Users may be assigned to groups by the administrator. Users within a group have access to all data generated by that group.
Revision control	All methods and reports are maintained under strict revision control
Audit trail	Configurable audit trail tracks all events including deleted reports
Electronic signature	Reports can be signed by users with the assigned rights, e.g. approval. These reports are then locked and cannot be changed.
<b>Hardware Requirements</b>	
Processor	Pentium III or better
Memory	256 MB RAM, min. 10 GB Harddisk
Operating system	Windows NT 4.0 SP6, Windows 2000 SP4 or Windows XP
All specifications may be subject to change for technical reasons.	

## Ordering Information

UVSX	UVSX 21CFR Part 11 Compliant Software for UVIKON XS and XL
UVSX-Lite	UVSX Software for UVIKON XS and XL for applications where 21 CFR Part 11 compliance is not required