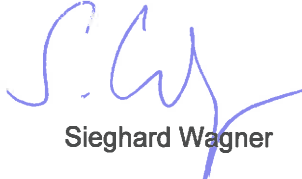


Vision 4.1 Patch 1 for NIR spectroscopy

Audit Date:	13.01.2017 ¹
Auditor:	Sieghard Wagner, mech. Engineer (grad.), Chemengineering Business Design GmbH
Audit Target:	Compliance check against the requirements of 21 CFR Part 11 for <i>Vision 4.1 Patch 1</i> software which is used to control devices for NIR spectroscopy.
Description:	PC software for controlling NIR spectroscopy devices: create operations methods, instrument configurations, libraries and equations, perform analysis (record NIR spectra), data acquisition, evaluation against library, and archiving in a database. The software was developed by Metrohm AG in accordance with the ISO 9001 requirements regarding design, manufacturing and maintenance.
Investigation:	The functions and properties of the above software system are audited against the requirements of 21 CFR Part 11 and its current interpretations. During the audit the following items were examined: validation, documentation, audit trail, electronic copies, access rights, user access, password, access violation, sequence of steps, plausibility, device check, data encryption, electronic signature.
Operator Responsibility:	Compliance with 21 CFR Part 11 requires an appropriate operational environment. It is the operations responsibility to provide a compliant environment regarding: <ul style="list-style-type: none">• technical environment, data management• training• administration• Standard Operating Procedures (SOP).
Summary:	The software is compliant to the following 21 CFR Part 11 requirements: <ul style="list-style-type: none">• 11.10 (b), (d), (e), (f), (g), (h)• 11.50, 11.70• 11.300 (a) The software is compliant to the following 21 CFR Part 11 requirements with support of the operator: <ul style="list-style-type: none">• 11.10 (a), (c), (i), (j), (k)• 11.100 (a), (b), 11.200 (a), 11.300 (b), (c), (d) The software supports electronic signature.


Sieghard Wagner

¹ This 21 CFR Part 11 certificate is based on an on-site audit performed January, 13th 2017. Subject of this audit was the software version 4.1 Patch 1 with all compliance features enabled.