

Vision Air 2.0 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 Air 2.0</i> software which is used to control devices for NIR spectroscopy.
Description:	<p>PC software for controlling NIR spectroscopy devices: create operating procedures, parameter profiles, and prediction models, perform analysis (record NIR spectrum), data acquisition, evaluation against library, and archiving in a database.</p> <p>The software was developed by Metrohm AG in accordance with the ISO 9001 requirements regarding design, manufacturing and maintenance.</p>
Investigation:	<p>The functions and properties of the above software system are audited against the requirements of 21 CFR Part 11 and its current interpretations.</p> <p>During the audit the following items were examined:</p> <ul style="list-style-type: none">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:	<p>Compliance with 21 CFR Part 11 requires an appropriate operational environment. It is the operations responsibility to provide a compliant environment regarding:</p> <ul style="list-style-type: none">technical environment, data managementtrainingadministrationStandard Operating Procedures (SOP).
Summary:	<p>The software is compliant to the following 21 CFR Part 11 requirements:</p> <ul style="list-style-type: none">11.10 (b), (d), (e), (f), (g), (h)11.50, 11.7011.300 (a) <p>The software is compliant to the following 21 CFR Part 11 requirements with support of the operator:</p> <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) <p>The software supports electronic signature.</p>


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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 2.0 with all compliance features enabled.