

916 Ti-Touch

5.916.0046



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Auditor:	Sieghard Wagner, mech. Engineer (grad.), Chemengineering Germany GmbH
Audit Target:	Compliance check of the <i>916 Ti-Touch</i> software (Version 5.916.0046) against the 21 CFR Part 11 requirements.
Description:	<p><i>916 Ti-Touch</i> is a compact titration system for volumetric titration – in the class of stand-alone systems for routine analysis – with touch-sensitive display for processing methods, analysis (titration, measurements), data acquisition, evaluation, and reporting. <i>916 Ti-Touch</i> can be integrated in an automation system with Sample Processors.</p> <p><i>916 Ti-Touch</i> was developed by the Metrohm AG in accordance with 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 management• Training• Administration• Standard 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), (f)• 11.50, 11.70• 11.300 (a) <p>The software is compliant with the following 21 CFR Part 11 requirements with support of the operator:</p> <ul style="list-style-type: none">• 11.10 (a), (c), (e), (g), (h), (i), (j), (k)• 11.100 (a), (b), 11.200 (a), 11.300 (b), (c), (d), (e) <p>The software supports electronic signature.</p>