

## 917 Coulometer

5.917.0026



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<b>Auditor:</b>	Sieghard Wagner, mech. Engineer (grad.), Chemengineering Germany GmbH
<b>Audit Target:</b>	Compliance check of the <i>917 Coulometer</i> software (Version 5.917.0026) against the 21 CFR Part 11 requirements.
<b>Description:</b>	<p><i>917 Coulometer</i> is a compact titration system for coulometric Karl Fischer 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>917 Coulometer</i> can be integrated in an automation system with 885 Compact Oven SC.</p> <p><i>917 Coulometer</i> was developed by the Metrohm AG in accordance with ISO 9001 requirements regarding design, manufacturing, and maintenance.</p>
<b>Investigation:</b>	<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"><li>Validation, documentation, audit trail, electronic copies, access rights, user access, password, access violation, sequence of steps, plausibility, device check, data encryption, electronic signature.</li></ul>
<b>Operator Responsibility:</b>	<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"><li>• Technical environment, data management</li><li>• Training</li><li>• Administration</li><li>• Standard Operating Procedures (SOP).</li></ul>
<b>Summary:</b>	<p>The software is compliant to the following 21 CFR Part 11 requirements:</p> <ul style="list-style-type: none"><li>• 11.10 (b), (d), (f)</li><li>• 11.50, 11.70</li><li>• 11.300 (a)</li></ul> <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"><li>• 11.10 (a), (c), (e), (g), (h), (i), (j), (k)</li><li>• 11.100 (a), (b), 11.200 (a), 11.300 (b), (c), (d), (e)</li></ul> <p>The software supports electronic signature.</p>