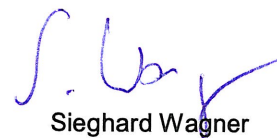


## 900 Touch Control

<b>Audit Date:</b>	19.04.2013 <sup>1</sup>
<b>Auditor:</b>	Sieghard Wagner, mech. Engineer (grad.), Chemengineering Business Design GmbH
<b>Audit Target:</b>	Compliance check of the device <i>900 Touch Control</i> (Version 5.900.0020) for controlling Titrandos against the requirements of 21 CFR Part 11.
<b>Description:</b>	<p>Device for controlling Titrandos. Creation of methods, carrying out determinations (titrations and measurements), data acquisition, and evaluation.</p> <p>The software was developed by Metrohm Ltd. in accordance with the ISO 9001 requirements regarding design, manufacturing and maintenance.</p>
<b>Investigation:</b>	<p>The functions and properties of the mentioned software system are audited with the requirements in 21 CFR Part 11 and the current interpretations.</p> <p>During the audit the following items were examined:</p> <p>Validation, documentation, audit trail, electronic copies, access rights, user access, password, access violation, sequence of steps, plausibility, device check, data encryption, electronic signature.</p>
<b>Operator Responsibility:</b>	<p>The compliance with the requirements of 21 CFR Part 11 can only be met together with the operational environment. The requirements for such an environment are:</p> <ul style="list-style-type: none"><li>• technical environment, data management</li><li>• training</li><li>• administration</li><li>• SOPs (Standard Operating Procedures).</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), (g), (h)</li><li>• 11.50, 11.70</li><li>• 11.300 (a)</li></ul> <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"><li>• 11.10 (a), (c), (e), (i), (j), (k)</li><li>• 11.100 (a), (b)</li><li>• 11.200 (a), 11.300 (b), (c), (d).</li></ul>



Sieghard Wagner

<sup>1</sup> This 21 CFR Part 11 assessment is based on an audit performed March the 2<sup>nd</sup> 2004. Subject of this audit was the software version 5.840.0120. According to Metrohm AG management (development and QA), the implemented changes in the current version are not relevant with regard to 21 CFR Part 11 or compliant with 21 CFR Part 11 (see Release Notes 8.840.8009EN, 8.900.8004EN, 8.900.8009EN, 8.900.8016EN). Therefore, this update does not require a physical re-audit.