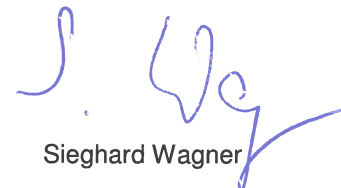


900 Touch Control

Date:	23.10.2015 ¹
Auditor:	Sieghard Wagner, mech. Engineer (grad.), Chemengineering Business Design GmbH
Audit Target:	Compliance check of the device <i>900 Touch Control</i> (Version 5.900.0032) for controlling Titrandos against the requirements of 21 CFR Part 11.
Description:	<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 AG in accordance with ISO 9001 requirements regarding design, manufacturing and maintenance.</p>
Investigation:	<p>The functions and properties of the mentioned software system are audited with the requirements of 21 CFR Part 11 and the 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 the requirements of 21 CFR Part 11 can be met in connection with the operational environment only. The requirements for such an environment encompass:</p> <ul style="list-style-type: none">technical environment, data managementtrainingadministrationStandard Operating Procedures (SOP).
Summary:	<p>The software is compliant with the following 21 CFR Part 11 requirements:</p> <ul style="list-style-type: none">11.10 (b), (d), (f), (g)11.50, 11.7011.300 (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), (h), (i), (j), (k)11.100 (a), (b)11.200 (a), 11.300 (b), (c), (d).


Sieghard Wagner

¹ This 21 CFR Part 11 certificate is based on a physical audit performed March the 2nd 2004. Subject of this audit was the software version 5.840.0120. According to Metrohm AG management (development and QA) all implemented changes in the following versions – including the current version – are not relevant with regard to 21 CFR Part 11 or 21 CFR Part 11 compliant (see Release Notes 8.840.8009EN, 8.900.8004EN, 8.900.8009EN, 8.900.8016EN, 8.900.8017EN, 8.900.8019EN, 8.900.8021EN). Therefore, this update does not require a physical re-audit.