

Project 0.2.0.263.786
Audit Report: 21 CFR Part 11



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tiamo 1.2 for titration

Audit Date:	02.03.2004 ¹
Auditor:	Dipl. Ing. (FH) Elmar Harringer, Chemgineering GmbH
Audit Target:	Compliance check of <i>tiamo</i> 1.2 software for controlling titration devices against the requirements of 21 CFR Part 11.
Description:	<p>PC software for controlling titration devices. Creation of methods, carrying out determinations (titrations and measurements), data acquisition, evaluation, and archiving in a database.</p> <p>The above software was developed and manufactured in accordance with the requirements demanded by the ISO 9001 quality system regarding the design, manufacture and servicing of Metrohm instruments.</p>
Investigation:	<p>The functions and properties of the above 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: validation, documentation, audit trail, electronic copies, access rights, user access, password, access violation, sequence of steps, plausibility, device check, data encryption, digital signature.</p>
Operator Responsibility:	<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">• technical environment, data management• training• administration• SOP (Standard Operating Procedures)
Summary:	<p>The software is compliant to the following 21 CFR Part 11 requirements:</p> <ul style="list-style-type: none">• 11.10.(a), (b), (d), (e), (f), (g), (h)• 11.30, 11.50, 11.70• 11.100 (a), 11.200 (a), 11.300 (a), (b), (d) <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 (c), (i), (j), (k)• 11.100 (b), 11.300 (c), (e) <p>The software is supporting digital signature.</p>

¹ The audit was carried out with *tiamo* version 1.0. The current software version does not contain any modifications regarding 21 CFR Part 11. (01. September 2006)