

Audit Report: 21 CFR Part 11



Metrohm Ltd.
CH-9100 Herisau
Switzerland
Tel. +41 71 353 85 85
Fax +41 71 353 89 01
www.metrohm.com

StabNet 1.1 for control of stability measurement devices

Audit Date:	16.09.2014 ¹
Auditor:	Sieghard Wagner, mech. engineer (grad.), Chemengineering Business Design GmbH
Audit Purpose:	Proof that the <i>StabNet 1.1</i> software, used for the control of stability measurement devices, is in compliance with 21 CFR Part 11.
Description:	<p><i>StabNet</i> is a PC software for the control of stability measurement devices. It features creating methods, performing single and multiple analyses, evaluating data (results, statistics, limit monitoring) and generating reports.</p> <p>The software was developed by Metrohm Ltd. in accordance with ISO 9001 requirements regarding design, manufacturing and maintenance.</p>
Investigation:	<p>The functions and properties of the system mentioned above are audited in regards to the requirements of 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 violations, sequence of steps, plausibility, device check, data encryption, electronic signature.</p>
Operator Responsibility:	<p>Compliance with the requirements of 21 CFR Part 11 can only be met in connection with the operational environment. The requirements for such an environment encompass:</p> <ul style="list-style-type: none">• Technical environment, data management• Training• Administration• Standard 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), (e), (f), (g)• 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), (h), (i), (j), (k)• 11.100 (a), (b), 11.200 (a), 11.300 (b), (c), (d). <p>The software supports electronic signatures.</p>

Sieghard Wagner

¹ This 21 CFR Part 11 certificate is based on a physical audit of StabNet 1.0, performed March the 7th 2012. According to Metrohm AG, 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 8.103.8025EN). Therefore, this update does not require a physical re-audit.