

Audit Report: 21 CFR Part 11

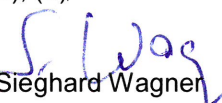


Metrohm AG  
CH-9100 Herisau  
Switzerland  
Tel. +41 71 353 85 85  
Fax +41 71 353 89 01  
<https://www.metrohm.com>

## 915 KF Ti-Touch

5.915.0044

- Audit Date:** 05-November-2021<sup>1</sup>
- Auditor:** Sieghard Wagner, mech. Engineer (grad.), Chemengineering Business Design GmbH
- Audit Target:** Compliance check of the *915 KF Ti-Touch* software (Version 5.915.0044) against the 21 CFR Part 11 requirements.
- Description:** *915 KF Ti-Touch* is a compact titrator for volumetric 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. *915 KF Ti-Touch* can be integrated in an automation system with Sample Processors.
- 915 KF Ti-Touch* was developed by the Metrohm AG in accordance with ISO 9001 requirements regarding design, manufacturing, and maintenance.
- Investigation:** The functions and properties of the above software system are audited against the requirements of 21 CFR Part 11 and its current interpretations.
- 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, electronic signature.
- Operator Responsibility:** Compliance with 21 CFR Part 11 requires an appropriate operational environment. It is the operations responsibility to provide a compliant environment regarding:
- Technical environment, data management
  - Training
  - Administration
  - Standard Operating Procedures (SOP).
- Summary:** The software is compliant to the following 21 CFR Part 11 requirements:
- 11.10 (b), (d), (f), (g)
  - 11.50, 11.70
  - 11.300 (a)
- The software is compliant with the following 21 CFR Part 11 requirements with support of the operator:
- 11.10 (a), (c), (e), (h), (i), (j), (k)
  - 11.100 (a), (b), 11.200 (a), 11.300 (b), (c), (d), (e).
- The software supports electronic signature.

  
Sieghard Wagner

<sup>1</sup> This 21 CFR Part 11 assessment is based on a remote audit performed on May 8, 2017. Subject of this audit was the firmware version 5.915.0040 with all compliance features enabled. 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 compliance (please refer to the Release Notes 8.915.8008 EN, 8.915.8010 EN, 8.915.8011 EN, and 8.915.8015 EN). Therefore, this update does not require a formal re-audit.