

Audit Report: Categorisation acc. to GAMP

900 Touch Control



Metrohm Ltd.

CH-9101 Herisau

Switzerland

Tel. +41 71 353 85 85

Fax +41 71 353 89 01

www.metrohm.com

Date: 30.08.2011

Author: Sieghard Wagner, mech. Engineer (grad.), Chemengineering Business Design GmbH

Goal: Classification of the *900 Touch Control* software into one of the GAMP software categories.

Description: *900 Touch Control* is an operation and control unit with touch-sensitive display for processing of methods, analysis, data acquisition, evaluation and reporting. The software was developed by Metrohm AG in accordance with the ISO 9001 requirements regarding design, manufacturing and maintenance.

Categorisation: The *900 Touch Control* software is a "Non-Configured Product" – as such it is categorized into **GAMP software category 3**.

Justification:
All functions required for operation are available in the product – no configuration is necessary in order to conform to user-site business processes.

The existing configuration is limited to:

- Maintenance of master data (methods, reagents, sensors, templates, etc)
- Setup of technical parameters (devices, etc)
- Creation and maintenance of the authorization concept including security settings (user, dialog settings, etc).

The creation and modification of methods in particular, is based on build-in standard system functionality. During normal system operation, methods are adapted to specific analytical procedures on a case by case basis. This has to include appropriate checks and verifications, especially of all calculations and reports included – if applicable. These measures are to be implemented as part of the operational controls in order to maintain the validated state.

A handwritten signature in blue ink, appearing to read 'S. Wagner', written over the printed name.

Sieghard Wagner