

Declaration of Conformity

Software Validation

for the PC program

Metrodata 763 PC Software 1.0

Description

The 763 PC Software 1.0 is required for the operation of the 763 PVC Thermomat; it is contained on the 6.6037.000 CD ROM included in the scope of delivery. This program runs under Windows™ NT (recommended, especially if several instruments are connected), Windows™ 95 and Windows™ 98 operating systems.

The 763 PC Software 1.0 allows a maximum of 4 PVC Thermomats to be controlled. The following possibilities exist for connecting these instruments to serial PC interfaces:

- Connection to built-in COM interfaces on the PC
- Connection to an additional built-in interface extension board
- Connection to a softswitch (order number: 2.145.0014 for 230 V, 2.145.0015 for 115 V) which is connected to one of the COM interfaces.

Scope of delivery of Metrodata 763 PC Software 1.0

6.6037.000 CD ROM containing Metrodata 763 PC Software 1.0

8.763.8007 Registration card (German/English) for Metrodata 763 PC Software 1.0

The above software was developed in accordance with the requirements of the ISO 9001 quality system regarding the design, testing and servicing of Metrodata software. The relevant procedures are described in the following documents archived by Metrohm:

- System function specifications
- Module specifications
- Unit test specifications
- Source code listing
- Software test specifications
- Software test reports

The technical specifications are documented in the instruction manual.

The software was validated with respect to functionality, analytical performance and accuracy of results. The software functions are documented in the instruction manual.

Herisau, 10th February 2000



Dr. J. Frank
Development Manager



Ch. Buchmann
Production and
Quality Assurance Manager



Metrohm Ltd.
CH-9101 Herisau
Switzerland
Tel. +41 71 353 85 85
Fax +41 71 353 89 01
www.metrohm.com

Quality Management Principles

Metrohm Ltd. holds the ISO 9001 Certificate, registration number 10872-03, issued by SQS (Swiss Association for Quality and Management Systems). Internal and external audits are carried out periodically to assure that the standards defined by Metrohm's QM Manual are maintained.

The steps involved in the design, manufacture and servicing of instruments are fully documented and the resulting reports are archived for ten years. The development of software for PCs and instruments is also duly documented and the documents and source codes are archived for at least 15 years. Both remain the possession of Metrohm. A non-disclosure agreement may be asked to be provided by those requiring access to them.

Both hardware and software are developed according to the standards established for the application of the GLP principles to computer-assisted systems. Accordingly, hardware and software are suitable for use in a GLP-compliant environment.

The implementation of the ISO 9001 quality system is described in Metrohm's QM Manual, which comprises detailed instructions on the following fields of activity:

Instrument development

The organization of the instrument design, its planning and the intermediate controls are fully documented and traceable. Laboratory testing accompanies all phases of instrument development.

Software development

Software development occurs in terms of the software life cycle. Tests are performed to detect programming errors and to assess the program's functionality in a laboratory environment.

Components

All components used in the Metrohm instruments have to satisfy the quality standards that are defined and implemented for our products. Suppliers of components are audited by Metrohm as the need arises.

Manufacture

The measures put into practice in the production of our instruments guarantee a constant quality standard. Production planning and manufacturing procedures, maintenance of production means and testing of components, intermediate and finished products are prescribed.

Customer support and service

Customer support involves all phases of instrument acquisition and use by the customer, i.e. consulting to define the adequate equipment for the analytical problem at hand, delivery of the equipment, user manuals, training, after-sales service and processing of customer complaints. The Metrohm service organization is equipped to support customers in implementing standards such as GLP, GMP, ISO 900X, in performing Operational Qualification and Performance Verification of the system components or in carrying out the System Validation for the quantitative determination of a substance in a given matrix.