

# Declaration of Conformity

for the instrument

## 714 IC Metrodata for Windows™



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### Description

<b>2.714.0310</b>	714 IC Metrodata for 2 channels
<b>2.714.0320</b>	expansion to 4 channels
6.6027.158	Demo version of IC Metrodata PC software

Demo versions are original versions with examples but do not allow the acquisition of chromatograms.

«714 IC Metrodata for Windows™» comprises the 1.714.0310 PC Board, the 6.2145.010 Dongle and the 6.6027.153 Software. It is a versatile integrator system for all chromatographic methods, especially ion chromatography. The evaluation software is based on Windows 95 and supports the corresponding functions such as multitasking and easy export of data to other Windows applications. «IC Metrodata for Windows™» offers the following possibilities:

#### Hardware

- 1.714.0310 PC Board for analog/digital conversion with a resolution of 24 bit and a voltage range of  $\pm 2.5$  V, data acquisition rate up to 60 points/s.
- Two entry channels that can be used simultaneously or independently from each other. Expansion to four channels is possible with 2.714.0320.

#### Software

- Data acquisition via methods that contain the corresponding acquisition and evaluation parameters.
- Real-time monitoring of chromatograms during recording.
- Various possibilities for graphical representation and manual reprocessing of chromatograms.
- Calibration with internal or external standard method, multipoint calibrations with linear, quadratic or cubic regression.
- Free formatting of result printouts.
- Automatic reprocessing of evaluated chromatograms («Queue»).
- Export and import possibilities for chromatograms and reports.
- Remote control of IC instruments.

The technical specifications are documented in the instruction manual (8.714.805X).

714 IC Metrodata was validated with respect to functionality, analytical performance and accuracy of results. Its functions are documented in the instruction manual and the help file.

Herisau, 8<sup>th</sup> January 1999

Dr. J. Frank  
Development Manager

Ch. Buchmann  
Production and  
Quality Assurance Manager

## Quality Management Principles

Metrohm Ltd. holds the ISO 9001 Certificate, registration number 10872-02, 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. Both remain the possession of Metrohm. A non-disclosure agreement may be asked to be provided by those requiring access to them.

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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 organisation 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 organisation 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.