



## Software package APT-COM™ 3 DataControlSystem compliant according FDA 21 CFR 11

Software package APT-COM for Windows for the linking of up to 30 units or controllers with the communication interface RS 232 or RS 422 for remote control, programming and data recording.

Versions of the APT-COM™ 3 DataControlSystem:

### APT-COM™ BASIC-EDITION

- ▶ Connection of one BINDER temperature chamber or measuring device with interface RS 232 or RS 422 to a PC
- ▶ Graphical program editor for comfortable remote programming of one temperature chamber
- ▶ Graphic recording of the controlled process parameter temperature, pressure, humidity or CO2 concentration
- ▶ Documentation when exceeding an adjustable tolerance limit
- ▶ Documentation of all system interventions
- ▶ Export of the data for printing or saving in spreadsheet

### APT-COM™ STANDARD-EDITION

All functions of BASIC Edition plus:

- ▶ Connection of up to 30 BINDER temperature chambers simultaneously
- ▶ Graphical program editor for comfortable remote programming
- ▶ Documentation of measurements as HTML files, HTTP webserver function for comfortable process control
- ▶ E-mail notification for limit over- / under run using Simple Mail Transfer Protocol (SMTP)
- ▶ Integration under LIMS with i.e. Labview optional possible
- ▶ Programmable time based print function (daily, weekly, monthly)
- ▶ Variable print out in HTML / E-mail format
- ▶ Net work compatible
- ▶ Program operation also for constant value controllers (only for units with controller RD2)
- ▶ Manual data backup system

### APT-COM™ GLP-EDITION

All functions of STANDARD Edition plus:

- ▶ Documentation of the measurement data, safe against manipulation and in accordance to GLP/GMP
- ▶ Fully compliant according FDA 21 CFR Part 11
- ▶ Full password protection of all user
- ▶ Transfer of remote alarm via E-mail (or/and telephone, optional)
- ▶ System overview (control room function) over all units via TCP/IP protocol
- ▶ Unlimited number of users
- ▶ Automatic data backup system

### Recommended System Requirements:

- ▶ Windows 2000, XP
- ▶ Intel Pentium 4 min. 2 GHz or similar AMD

- ▶ 512 MB RAM • Network card 100 Mbit Ethernet
- ▶ Hard disk with at least 7200 rpm
- ▶ Graphic card with 16MB local RAM
- ▶ CD-ROM or DVD drive
- ▶ one free PCI slot with own interrupt (for optional COM-port extension)
- ▶ at least one free COM port with free interrupt
- ▶ 100 MB free hard disk memory (for program without measuring data)
- ▶ Screen resolution 1024x786, setting True color (32 bit)
- ▶ 19" tube monitor or similar TFT screen

These system requirements are recommended when using all features of APT-COM™ 3 DataControlSystem GLP Edition. For use of the Basic or Standard versions lower system requirements can be sufficient. If the system properties are not sufficient, the operating speed of APT-COM™ 3 will noticeably decrease.

The operating systems Windows 95, 98, and ME are not suitable for operating APT-COM™ 3 DataControlSystem. You can operate APT-COM™ 3 versions lower than 3.02.021 with the operating system Windows NT 4.0 (Service Pack 6). If you like to use also versions from 3.02.021 on with Windows NT 4.0, please contact the BINDER Service. BINDER recommends using Windows 2000 with Service Pack 4 or Windows XP Professional from Service Pack 2 on.

APT-COM™ 3 DataControlSystem has been tested with German and English operating systems. When operating it with operating systems of other languages, the BINDER GmbH excludes liability for correct function. If a system qualification has been performed using BINDER qualification documents, the correct function of APT-COM™ 3 DataControlSystem can be assumed even when using it with an operating system of a different language.

APT-COM™ 3 scales in relation to the offered system capacity, i.e., you can increase operating speed, if necessary, by increasing system capacity (e.g. faster processor, more working memory).

Depending on any further installed software on your system, higher system requirements than the minimum requirements listed might be needed. Operating e.g., a virus scanner can remarkably decrease computer performance resulting in considerably lower processing speed of the APT-COM™ 3 processes. Having connected many (up to 30) temperature chambers, the actualization interval of 1 min might not be respected. For optimal use of all components with maximum speed, BINDER recommends a hardware configuration according to GxP.

APT-COM™ 3 DataControlSystem supports multicore systems. The software strongly scales with the number of cores in the system. When choosing a processor we therefore generally recommend using a multicore system as preferable compared to a single core system.

#### **Additional system requirements for system validation according to GxP (GLP Edition):**

- ▶ APT-COM™ 3 GLP Edition
- ▶ Only Windows 2000 or XP Professional with actual Service Pack and actual Microsoft patches
- ▶ Intel chipset
- ▶ Intel network card
- ▶ At least UDMA-66 hard disk with 7200 rpm or RAID1
- ▶ Intermission free power supply for all PC components, and the mains unit of the converter e.g. via special battery buffered power installation or buffer unit attached to the PC system (recommended).

#### **Notes:**

It is possible to install APT-COM™ 3 DataControlSystem on a network server. The resulting losses in security and speed need to be discussed and weighted by the customer in advance. A validation of the total system by BINDER is no more possible in this case.

The system requirements are given for the measurement computer with APT-COM™ 3 running as well as for the monitoring computer with the monitoring software Watch Tool running.

Verify if any network access restrictions exist for your computer. For installation of APT-COM™-Software as well as for driver installation in case of a needed RS232 extension port you might need administrator rights.

Important note to avoid data losses: To ensure complete data acquisition and continuation of program operation during and after a power failure, we recommend to connect the mains of PC and all hardware components to a break free battery buffered power feeding.

Each mains unit and the control board have an input power of less than 10 W.

BINDER excludes each liability for data overrun.