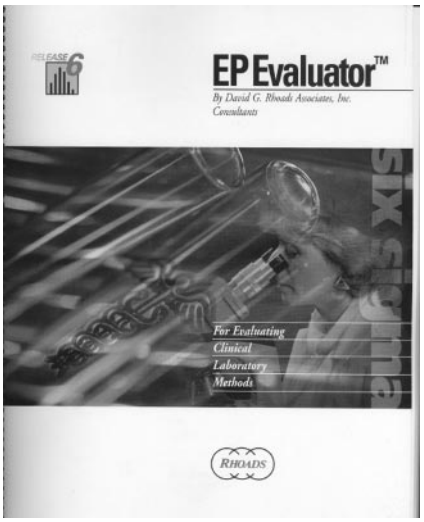
**EP Evaluator, CD ROM, Release 6.** Kennett Square, PA: David G. Rhoads Associates, CD ROM, manual of ~415 pages plus 7 NCCLS Guidelines, 2004, price varies (as reviewed, $2795.00).




EP Evaluator, Release 6 (EE6) is a Windows-based package of statistical applications for clinical laboratory method evaluation.

Minimum system requirements are an IBM-compatible PC with Pentium CPU, 32-bit Windows operating system, 32 MB of RAM, and 50 MB of hard drive space. The package includes a CD ROM, user's manual, and the associated NCCLS documents (NCCLS EP5-A, EP7-A, EP9-A2, EP10-A2, EP12-A, C28-A, and GP10-A). For this evaluation, the Professional version of the software was installed and run on a Pentium 4 platform operating under Windows XP; no problems were noted at installation, although a few isolated errors did occur during software operation.

The spiral-bound user's manual contains instructions for program operation and file management functions. There are separate chapters for each of the 20 statistical modules, and sample data sets (many of which match those preloaded into the software) with corresponding images of parameter, data entry, and results screens effectively illustrate program operation. Several additional chapters offer valuable guidance for the design and interpretation of method-evaluation studies. I did note some inconsistency between the user's manual and the software, but the manual is generally well organized and clearly written.

Input of data is accomplished through several routes, including manual entry, transfer from previous versions of EP Evaluator, copy/import from spreadsheet files, or direct capture from clinical analyzers via user-supplied instrument interface programs. Data may also be transferred from EE6 to spreadsheet programs by copying/pasting values or by exporting to comma-separated value (CSV) files.

EE6 offers real-time graphical display of results as data are entered, and individual results may be excluded from calculations by right-clicking on the appropriate plot point. For many of the graphs, clicking on any point within the graph will automatically highlight its corresponding numeric value in the results grid; this is a convenient tool by which to quickly and easily identify any point within the graph.

Most of the modules have a similar layout, featuring module overview, parameter, and experiment detail screens in which selection of experiment, specification of parameters, data entry, data analysis, and file utilities are performed. "Projects" can be defined to create distinct workspaces for organizing and storing data from related studies. Another option allows establishment of "policies"; here, parameters are entered once for a series of experiments rather than in individual module parameter screens. Help screens are abundant throughout and provide a comprehensive guide to both general and module-specific operations. Each module is capable of generating a summary report containing the data, statistical analysis, and corresponding plot(s). In addition, several modules include a very useful "Report Interpretation Guide", a printable document that supplements the analysis output with module-specific guidance and definitions. The report may be queued directly to a printer or saved in any of several graphic file formats (e.g., PDF, JPEG, and PNG). A particularly handy feature allows the user to "clip" a portion of the report, such as a table or graph, for insertion into applications outside of EP Evaluator.

Individual applications are accessed from the main program screen, where they are organized by function into six main categories: Precision, Linearity and Calibration Verification, Method Comparison, Sensitivity, Reference Interval, and Other. The two precision modules perform similar calculations on replicate results, including mean, overall SD, and CV. Additionally, calculations for within-run, between-run, and between-day statistics are available in the Complex Precision module. Assessment of accuracy, precision, linearity, reportable range, calibration verification, and probability of proficiency test failure are performed by the Linearity and Calibration Verification module. Graphical representation of the results in the form of scatter, recovery, and residual plots is provided, with an optional "History" function that allows up to three sets of linearity data to be plotted on the same graph.

There are several useful applications for method comparison, including the Alternate Method Comparison module, which provides a framework for standard method-comparison studies, regression statistics ("regular", Deming, and Passing–Bablok), and scatter and bias (including Bland–Altman) plots. The *t*-test is not included as a default, but it can be calculated if desired by selection of that option in the program's file preferences menu. The EP9 module follows NCCLS guidelines for method-comparison studies using duplicate sample analysis. The statistical analyses performed are in keeping with those recommendations, but the software neglects to provide the NCCLS-recommended scatter plot for individual test method values vs the mean of the corresponding duplicate measurements of the comparative method.

The Hematology Studies module is a method-comparison tool specific for hematologic applications, in which multiple analytes for two or more instruments are examined simultaneously and results are collated into a single report. In addition to providing results of linear regression analysis for all analytes (e.g., hemoglobin, hematocrit, cell counts, and automated differential counts), this module constructs truth tables and lists false-negative and false-positive results when comparisons are performed with the manual white cell differential count as a reference method. I found this application to be the most difficult to navigate in EE6, in part because of its distinctly different format. In contrast to most of the other modules, here there are no parameter screens in which to enter instrument/method information; this must instead be handled through definition of a policy. To further complicate matters, analytes are referred to as "parameters" in this module only, whereas the same term is used to describe instrument and method properties in all other applications. It is fortunate that a tutorial specific to the Hematology Studies module is included in the user's manual because it is unlikely that the average user could successfully execute this module without such assistance.

Additional method-comparison modules are included and are suitable for qualitative, multiple-instrument, and glucose point-of-care testing applications. These are straightforward in operation and provide clear and informative summary reports containing an assortment of statistical parameters and graphical outputs.

EE6 calculates sensitivity two different ways: either by determining the lowest concentration significantly different from zero through use of instrument responses (e.g., absorbance units) of a zero and nonzero calibrator (analytical sensitivity) or by calculating the lowest concentration at which an analyte can be measured with acceptable precision (functional sensitivity).

In addition to statistical calculations (mean, median, and SD) provided in the Verification of Reference Interval module, the summary report includes results distribution displayed in both table and histogram formats. The Establishment of Reference Interval module features a comprehensive statistical summary of results from parametric, nonparametric (NCCLS C28-A), and transformed parametric analysis of data. A particularly useful option allows data to be partitioned or filtered by patient demographics. ROC studies may also be performed, where in addition to the usual ROC and dot plots, results for parameters such as sensitivity, specificity, efficiency, area under the curve, and predictive values are generated. A miscellaneous group of six modules rounds out the EE6 suite of statistical tools. Modules for Carryover, Interference, Cost per Test, Six Sigma Metrics (error budget analysis for random and systematic error), NCCLS EP10 Evaluation (preliminary evaluation of linearity, recovery, precision, carryover, and drift), and Performance Standards (for determining goals for total allowable error) are included in this category.

In summary, this software provides a comprehensive collection of statistical applications guaranteed to fit the needs of most clinical laboratories. Comprehensive and professional-looking summary reports are the norm for all modules. Overall, the program is straightforward to operate, although users should expect to have to rely heavily on program help functions and the manual to navigate the more complex modules. The single-user package is available in a number of flavors, ranging from "EE6 CLIA" (seven modules, at $495) to "EE6 Professional" (20 modules, as reviewed here, at $2795; the 10-user network version is $28 000). Purchase of the software includes telephone support for only 60 days; given the size and complexity of the program (and its hefty price tag), this is likely to be inadequate.

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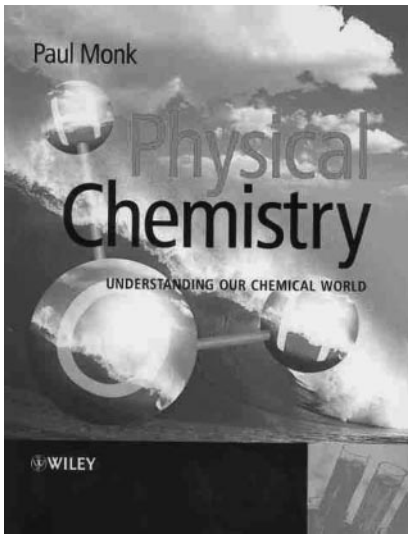
**Physical Chemistry: Understanding Our Chemical World.** Paul Monk. Chichester, West Sussex, England: John Wiley & Sons, Ltd., 2004, 618 pp., $44.95 (softcover). ISBN 0-471-49181-0.




I am all too aware that courses in physical chemistry are often not recalled with fond memories by those who go on to pursue careers in biology and medicine. Once at lunch with a former student and some of her young physician friends, I asked if physical chemistry wasn't one of the most valuable courses they had. After a period of quiet, one of them remarked that the textbook was good for propping up a table with one short leg, and another asked, "What is physical chemistry?"

As a teacher of physical chemistry for 40 years, using the various texts by Moore and then Atkins, Laidler, and others, I came to Monk's book with a great deal of prejudice favoring traditional ways of structuring the text. I noticed, at first glance, that Monk's approach is very different. For example, there is no chapter on