### Regulatory Requirements

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### EP Evaluator® Versions

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**Let the quality assurance of EP Evaluator® go to work for you.**

Download a free 30-day trial version of EP Evaluator software from our website:

www.epevaluator.com

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**While we (clinical labs) are but a small component of the total healthcare system, our data controls a large majority of the critical decisions.**

David Rhoads PhD
Creator of EP Evaluator®
Upgrade Your Lab’s Performance with the Simplest Elegance of EP Evaluator®

Your lab is busy; you need quality results quickly and reports that are ready to sign and deliver. And, you need it at a reasonable price that won’t break your budget. You need EP Evaluator.

Dr. David G. Rhoads, a board-certified clinical chemist designed the first EP Evaluator in 1991, to help laboratories meet all ACP and CLSI requirements for validating and validating. He chose the name EP because he needed based only on the features you need to look for. See page 4 for “Tips for Feature Use.”

EP Evaluator leads with the following features:

• EP Evaluator comes preloaded with over 800 statistical modules. You can use any one or all of these statistical modules to produce reports.
• EP Evaluator is a powerful and easy-to-use laboratory tool. It is easy to understand and easy to use.
• EP Evaluator is a powerful tool for improving your laboratory’s data analysis. It is easy to understand and easy to use.

EP Evaluator leads with the following features:

• EP Evaluator is so simple that are:
  • EP Evaluator is so simple that are:
  • EP Evaluator is so simple that are:
  • EP Evaluator is so simple that are:
  • EP Evaluator is so simple that are:

A relatively small percentage of a hospital or clinic budget is devoted to the clinical lab, yet more than 70% of the objective data contributing to patient care comes from the laboratory.

Four major additions to EP Evaluator Release 12.1 include:

1. A new option in the professional version, allows you to pull data directly from Instrument Manager without the need to install ODBC on theHost PC. This greatly simplifies the installation process while still providing a secured connection and easy entry of data into your experiments.
2. EP Evaluator can be licensed through your Instrument Manager provider for a simplified renewal process with only one invoice, one PO and no annual activation code. This applies to the network professional version only and includes the Virtual Training class at no additional charge.
3. An additional composite report has been added. The current composite report groups the results by experiment where this new report groups the results by the analyte. This allows for easier Medlab review as all the pertinent information regarding the analyte is along together.
4. Instrument and analyte names up to 12 characters are now accepted for the accommodation of many of the toxicology tests now being performed by Mass Spec, particularly those in toxicology.

“EP Evaluator is so simple that are:

One of the tests I perform is testing software. This month’s journal of EP Evaluator® and just completed my testing. The software produced exactly the results I was looking for and has no problems whatsoever. Thanks for delivering a product that is testable... and just completing a quality inspection.”

Support and Training

When purchasing the EP Evaluator software product, you receive a complete package from the top source for clinical laboratory data. Diagnostics provides software “how to” videos available on the company website. Focused on a number of statistical modules, recorded webinars and training through a highly skilled customer support department. For customer interest, if a module is more in-depth training. Data innovations offers a virtual classroom. The virtual classroom training allows users to gain knowledge and expertise through hands-on exposure to the most updated statistical modules within EP Evaluator. This training is designed for new and current users with whom to improve their understanding and proficiency. Contact our sales representatives for additional information and pricing.

- William D. (Dave) Gray, Albuquerque, NM

Order Information

Contact the regional sales department.

North America
1200 Kirkland Avenue Suite 100
Sunnyvale, California, 94089
Tel: 408-688-2050 Technical support Tel: 855-816-9890

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Av. Jacques-Brei 1200, Buenos Aires, Argentina 50403
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Africa
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Kigali Telephone: +250 781 16 58 78 Technical support Tel: +250 781 16 58 78

System Requirements for data acquisition from Middleware

EP Evaluator®

EP Evaluator 11.0 or later

Other

Memory Specifications

Minimum of 128 MB of RAM for the application

Hand-Disk Specifications

Minimum of 200 MB of storage for non-network, single-user implementation

Minimum of 1 GB for networked, multi-user implementation

Support and Maintenance

Subscription Plan: Free software updates for the version to which you subscribe along with any new releases that are introduced during your subscription period. Access to technical support via email or phone Monday through Friday, excluding holidays from 9 am to 5 pm EST/EDT.

Product Training

Interactive Webinars and Advanced Workshops on selected EP Evaluator topics are available. Consult our website or call for further information and schedules.

Order Information

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Africa
34, av. Jacques-Brei 71
Kigali Telephone: +250 781 16 58 78 Technical support Tel: +250 781 16 58 78

System Requirements for EP Evaluator®

Operating Systems
Windows: 7 (32-bit and 64-bit)
Windows Server 2008 (32-bit)
Windows: 7 (32-bit and 64-bit)
Windows Server 2012 (32-bit and 64-bit)
Windows: 10 (32-bit and 64-bit)
Windows Server 2016

Memory Specifications

A minimum of 128 MB of RAM for the application

Hand-Disk Specifications

Minimum of 200 MB of storage for non-network, single-user implementation

Minimum of 1 GB for networked, multi-user implementation

Other

Monitor (minimum resolution: 1024 x 768), Keyboard Mouse, Portable Printer, Adobe Reader or compatible program

Document ID: 1275 I Version 8.0

Phone: +32 2 332 24 13

Fax: +32 2 770 62 22

Email: sales@dataevaluation.com

TM

www.dataevaluation.com

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Upgrade Your Lab’s Performance with the Simplex of EP Evaluator®

Your lab is busy; you need quality results quickly and reports that are ready to sign and deliver. And, you need it at a reasonable price that won’t break your budget. You need EP Evaluator.

EP Evaluator leads with the following features:

• Four Lab Management modules.
• 21-CH Part 11 (audit trail) compliance.
• Definitions of user groups control access to specific projects. For example, chemistry users at one site will not be able to access hematology data at site B. Access may be allowed to data for other modules.
• Built-in backup and restore.
• Copy data sets from spreadsheets.
• Many ways to capture data from instruments so you can import your data without having to enter it manually.

Productivity Tools

• Perform calculations for 100 or more experiments at one time.
• Organization of projects so you can see instantly those that passed and failed.
• Acquire data for instruments via middleware connectivity, files generated from instrument or those generated from LIS systems allowing you to import your data without having to enter it manually.
• Perform calculations for 100 or more experiments at one time.
• Organization of projects so you can see instantly those that passed and failed.
• Acquire data for instruments via middleware connectivity, files generated from instrument or those generated from LIS systems allowing you to import your data without having to enter it manually.

A relatively small percentage of a hospital or clinic budget is devoted to the clinical lab, yet more than 70% of the total cost of patient care comes from the laboratory.

Four major additions to EP Evaluator Release 12.1 include:

1. A new option in the professional version, allows you to pull data directly from Instrument Manager with the need to install ODBC on the thin client PC. This greatly simplifies the installation process and avoids a secured environment.

EP Evaluator can be licensed through your Instrument Manager providing for a simplified renewal process with only one invoice, one PO and no annual activation costs. This applies to the network professional version only and includes the Virtual Training class at no additional charge.

2. An additional composite report has been added. The current composite report groups the results by experiment where this new report groups the results by the analyst. This allows for easier Medical review as all the pertinent information regarding the experiment is available.

3. An instrument and analysis name up to 32 characters are now accepted for the accommodation of many of the toxicology tests now being performed by Mass Spec, particularly those in toxicology.

“Use of the tool is very easy. This morning I trained EP Evaluator on four laboratories and everyone was thrilled with the new system and its capabilities. No more headaches. Thanks for delivering a product that is trouble free... and for producing a quality application.”

- William D. (Dave) Gray, Albuquerque, NM

Support and Training

When purchasing the EP Evaluator software product, you receive a complete package from the go to source for the clinical laboratory. Data Innovations provides world “how to” videos available on the company website, focused training, and support through hands-on exposure to the most used statistical modules within EP Evaluator. This virtual training is designed for new and current users with the need to understand and proficiently use EP Evaluator. Contact your sales representative for additional information and pricing.

1. Simple Elegance of EP Evaluator
2. Instrument Manager
3. EP Evaluator

System Requirements for EP Evaluator®

Operating Systems

- Windows 10 (EE11.3 and up)
- Windows Server 2012R2 (EE11.2 and up) (64-bit)
- Windows 7 (32-bit and 64-bit)
- Windows Server 2008 (64-bit)
- Windows XP (SP2) (32-bit and up)
- Windows 2000 (SP3 and up) (32-bit and 64-bit)
- Windows 10 (1803 and up)

Memory Specifications

- A minimum of 128 MB of RAM for the application

Hard Disk Specifications

- Minimum of 200 MB for non-network, single-user implementation
- Minimum of 500 MB for networked, multi-user implementation

Other

- Monitor (720 x 480 minimum resolution), Keyboard, Mouse or local and networked Printer
- Adobe Reader or compatible program

System Requirements for data acquisition from Middleware

- EP Evaluator 11.0 or later
- Microsoft ODBC driver for Oracle 10c Serie 11.1.0.7 or later

Support and Maintenance

Subscript Plan – free software updates for the version to which you subscribe along with all new releases that are introduced during your subscription period. Access to technical support via email or phone Monday through Friday, excluding holidays from 9 am to 5 pm EST/EDT.

Product Training

Interactive Webinars and Advanced Workshops on selected EP Evaluator topics are available. Consult our web site at resources.epevaluator.com for further information and schedules.

Order Information

Contact the regional sales department.

North America

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Technical Support Tel: +32 2 770 62 23

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Melbourne, Victoria 3000
Sales Tel: +61 3 9671 7000
Technical Support Tel: +61 3 9671 5813

Data InnovationsTM

30 March 2018

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Data InnovationsTM

30 March 2018
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### Features

- Concurrent, Multiple User Access
- Composite Reporting
- Project Management
- Import Data from Middleware (ODBC)
- Security Audit Trail
- User Accounts for Network Security

### Accuracy and Linearity

**Clinical Linearity, Calibration Verification**
- Repetable Range
- Simple Accuracy
- Trueness
- CLSI EP6 Linearity

### Method Comparison

- Alternate-Baseline (Quantitated)
- CLSI EP A2 Method Comparison
- Two-Instrument Comparison
- Multiple-Device Comparison
- CLSI EP A3 Method Comparison

### Lab Management

- Cost Per Test
- Incident Tracking
- Inventory Management
- Competency Assessment

### Coagulation

- Geometric Mean
- PT/INR Method Comparison
- Manual INR Check
- Factor Sensitivity

### Other

- Performance Standards (TEa)
- Carryover
- Interference (CLSI EP7)
- Six Sigma Metrics
- Stability

### Reports

- Histogram and Descriptive Stats

Addresses requirements by regulatory legislation or organization.
What Makes EP Evaluator® Different from Other Software Products?

Through the years, Data Innovations, in partnership with Dr. Rhoads, has continued to develop technology for the clinical laboratory and in 1991 introduced the latest version of the cutting-edge Quality Assurance Software: EP Evaluator.

Four major additions to EP Evaluator Release 12.1 include:

1. A new option in the professional version, allows you to pull data directly from Instrument Manager: without the need to install ODL, on the Windows PC. This greatly simplifies the installation process while still providing a secured connection easy entry of data into your experiments.

2. EP Evaluator can be licensed through your Instrument Manager providing for a simplified renewal process with no one-time fee, no annual maintenance costs. This applies to the network professional version only and includes the Virtual Training classes at no additional charge.

3. An additional composite report has been added. The current composite report groups the result by experiment where these new report groups the result by the analyzer. This allows for easier Medical review as all the pertinent information regarding the analyzer is all together.

4. Instrument and analyte names up to 32 characters are now accepted so we can accommodate many of the many of the analyte names up to 32 characters.

A relatively small percentage of a hospital or clinic budget is devoted to the clinical lab, yet more than 90% of the data contributing to patient care comes from the laboratory.

Support and Training

When purchasing the EP Evaluator software product, you receive a complete package from the top source for clinical laboratory data. Data Innovations provides current “how to” videos available on the company website, a fully staffed and responsive technical support department with nearly 20 years experience.

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Technical support Tel: +32 2 332 24 14

System Requirements for EP Evaluator®

Operating Systems

Windows 7 (32 and 64-bit)
Windows Server 2008 (32-bit)
Windows 8 (32 and 64-bit)
Windows 10 (32 and 64-bit)

Memory Specifications

A minimum of 128 MB of RAM is required for the application

Hard Disk Specifications

Minimum of 200 MB for non-network, single-user implementation
Minimum of 340 MB for networked, multi-user implementation

Other

Monitor (1024 x 768 minimum resolution), Keyboard, Mouse and local or networked Printer
Adobe Reader or compatible program

Support and Maintenance

Subscription Plan – Free software updates for the version to which you subscribe along with any new releases that are introduced during your subscription period. Access to technical support via email or phone Monday through Friday, excluding holidays from 9 am to 8 pm EST/EDT.

Product Training

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Sales Tel: +32 2 332 24 14
Technical support Tel: +32 2 332 24 14

Dr. David G. Rhoads, a board-certified clinical chemist developed the first EP Evaluator in 1991, to help leverage the dollars coming into the lab in the most efficient way. With more than 30 years of experience in the clinical laboratory, Dr. Rhoads is a nationally recognized expert on quality assurance issues.

What Makes EP Evaluator® Simple and Useful

• Inspector-ready
• Easy to understand
• Well designed

What was true then is true today.

What was true then is true today.

Passed and failed.

Passed and failed.

Passed and failed.
### Regulatory Requirements

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<td>Composite Reporting</td>
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<td>Project Management</td>
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<td>Import Data from Middleware (ODBC)</td>
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<td>Security Audit Tool</td>
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<tr>
<td>User Accounts for Network Security</td>
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### Accuracy and Linearity

| Clinical Sensitivity, Calibration Verification | -        | -   | -   |        |
| Simple Accuracy                              | -        | -   | -   |        |
| Trueness                                    | -        | -   | -   |        |
| CLSI EP6 Linearity                           | -        | -   | -   |        |

### Method Comparison

| Alternate Linearity (Quantitative)          | -        | -   | -   |        |
| CLSI EP A2 Method Comparison               | -        | -   | -   |        |
| Two-Machine Comparison                      | -        | -   | -   |        |
| Multiple Instrument Comparison              | -        | -   | -   |        |
| Qualitative/Semi-Quantitative               | -        | -   | -   |        |

### Quality Assurance

| POC Glucose                                | -        | -   | -   |        |
| Hematology Studies                         | -        | -   | -   |        |
| Precision                                  | -        | -   | -   |        |

### Reference Interval

| Established                                | -        | -   | -   |        |
| Varied                                     | -        | -   | -   |        |
| ROC Plots                                  | -        | -   | -   |        |

### Sensitivity

| Limits of Blank (Analytical) *             | -        | -   | -   |        |
| Limits of Quantitation (Functional)*       | -        | -   | -   |        |

### Lab Management

| Cost Per Test                              | -        | -   | -   |        |
| Incident Tracking                          | -        | -   | -   |        |
| Inventory Management**                     | -        | -   | -   |        |

### Coagulation

| Geometric Mean and VR                      | -        | -   | -   |        |
| PT/INR Method Comparison                   | -        | -   | -   |        |
| Manual INR Checks                          | -        | -   | -   |        |

### Performance Standards (TEa)

| Carryover                                  | -        | -   | -   |        |
| CLSI EP A4 - Preliminary Evaluation        | -        | -   | -   |        |
| Interference (CLSI EP7) *                  | -        | -   | -   |        |

### Other

| Six Sigma Metrics                          | -        | -   | -   |        |
| Stability                                  | -        | -   | -   |        |

### Addresses requirements by regulatory legislation or organization

*Features can be provided from vendor in laboratory.
**Variable versions are compatible with physical servers only.