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Instrumentation & Software

5.1

Pyros Kinetix®

Incubating
Microplate Readers



Pyros Kinetix® Incubating Kinetic Tube Reader

The Pyros Kinetix® incubating tube reader is used with Pyrotell®-T lysate for performing kinetic turbidimetric endotoxin assays. Pyros Kinetix is designed for use with the Pyros® EQS software (software sold separately, see page 5.3).

The Pyros Kinetix tube reader offers a 96 tube capacity. Each well is independently timed, allowing the operator to add more samples while a run is in progress. A sensitivity as high as 0.001 EU/mL can be achieved with Pyrotell-T lysate, the most sensitive assay in the industry. *Note:* Borosilicate reaction test tubes are used in the Pyros Kinetix tube reader.

Pyros Kinetix Features

- Precise Temperature Control—incubator temperature is held to 37°C ± 0.5°C
- Solid State Design—no moving parts, low maintenance
- Low Cost Disposables

Advantages

- **Maximum Sensitivity:** As high as 0.001 EU/mL with Pyrotell-T lysate
- **Maximum Efficiency:** The instrument has a 96 tube format and allows sample addition, even after the run has been initiated
- **Ease of Use:** The instrument uses depyrogenated 8 x 75 mm glass test tubes which minimize the occurrence of contaminated wells, an issue frequently associated with plastic microplates
- **Flexible Testing:** Variable volumes and ratios can be utilized
- **Optimized Lysate Usage:** As little as 50 µL per test



#PKX02 ----- Pyros Kinetix Incubating Kinetic Tube Reader

#TTR01 -----Set of 2 acrylic test tube racks for 8 x 75 mm test tubes (Racks numbered 1–48 and 49–96)

#TK100 -----Pyrotube® 8 x 75 mm borosilicate glass, 100/pack

System Specifications

Computer Required ----- Intel® Pentium® 4 PC or newer; 2.4 GHz Windows® XP SP2 OS; 1 GB RAM (if stand alone); 40 GB HD, 800 x 600, 256 Color Monitor; serial port or compatible USB adapter required (for reader communication)

Capacity ----- 96 reaction test tubes

Power Requirement -----100–250 V, 50/60 Hz

Light Source ----- LED

Dimensions -----18 w x 3.75 h x 16 d in. (45.7 x 9.5 x 40.6 cm)

Weight -----27 lbs., 5 oz. (12.5 kg) (without external power supply)

Temperature Range ----- 37°C ± 0.5°C

Data Interface -----RS-232C

Data Transmission Format ----- ASCII character strings, 9600 baud

Registration ----- Instrument: CE EN 61010-1, EN 61326-2 1998

Power Supply: IEC601-1, IEC950, UL2601-1, UL1950, UL544, EN60950, EN60601-1, CSA22.2#125, CSA22.2#601-1, CSA22.2#950. TUV D303673901 (Cert# B970924072006)

Pyros Kinetix is designed for use with the Pyros EQS software.

For more information please visit our website at www.acciusa.com or contact Technical Services at (800) 848–3248.

Pyros® EQS

The Pyros EQS is intuitive, easy-to-use software that is designed specifically for endotoxin testing with the Pyros Kinetix tube reader.

Pyros EQS is a sophisticated 21 CFR Part 11 Compliant, software solution that provides efficient, accurate analysis and reporting. The software writes to an *Oracle® database, the industry standard in data security. It has multiple access levels for improved security, detailed audit trails, and built-in trending by date range, technician, sample type and LAL lot. The software provides enhanced reporting options, flexible operation modes and incorporates electronic signatures, as well as a supervisor sign-off on completed tests. The application also offers two choices for calculating Coefficient of Variations (CVs), and a new summarized Pass/Fail Report. For users who do not require 21 CFR Part 11 compliance, a more affordable version without the compliance features is also available (Cat #PEQS).

Pyros EQS Software

- #PEQS11 ----- Pyros EQS Software with Manual (21 CFR Part 11 Compliant)
- #PEQS11-VAL ----- -Pyros EQS Validation Protocol Package
- #PEQS ----- Pyros EQS Software with Manual (without part 11 compliance features)

Validation Protocols

Validation Protocols provide the end user with a comprehensive set of integrated documents to guide them through the system validation process. A Validation Plan outlines the tasks and documentation required to perform the validation. A Requirements Specification, the foundation of the validation process, clearly delineates the system's required functions and expected performance. Detailed instructions guide users step-by-step through the IQ/OQ, and PQ processes. Stress Test procedures are included as well as Change Control and Maintenance guides. A CD containing the protocol files in Microsoft® Word format allows users to edit the documents to meet their company's specific validation requirements. A Validation Protocol Package is available for the Pyros Kinetix tube reader.

**Cost for Pyros® EQS software includes first year annual Oracle® license fee. See ACC 2009 Price List for more information.*

Warranties, Parts and Service

Extended Warranty

The Extended Warranty for the Pyros Kinetix tube reader covers all parts and labor for one full year.

Service and Calibration

Associates of Cape Cod, Inc. performs repairs and recalibrations on the Pyros Kinetix tube reader. Please contact Customer Service for information about repairs and recalibrations at (800) 525-8378.

Extended Warranty

#WPKX2 -----one year

Service and Calibration

- #CAL02 ----- Calibration of Pyros Kinetix tube reader at ACC facility
- #CAL03 ----- On-Site Calibration of Pyros Kinetix tube reader

VersaMax™ Microplate Reader Incubating Microplate Reader*

The VersaMax microplate reader from Molecular Devices bridges the gap between the affordability of filter-based readers and the flexibility of monochromator-based systems.

Tunable, Filterless Flexibility

The VersaMax reader uses a grating monochromator to select the wavelength, so the exact wavelength needed can be selected for every assay. With a wavelength range from 340 to 850 nm, this is equivalent to having 510 free filters.

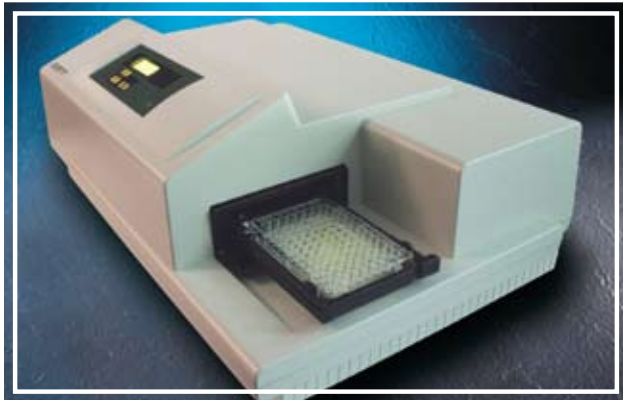
Exceptional Performance

The dual-wavelength readings report the actual absorbance at each wavelength, so you can analyze the data the way you want. The reader also provides controlled temperatures, up to 45°C, for kinetics at ambient and elevated temperatures.

Applications

In addition to endotoxin and glucan detection assays, the VersaMax reader may be used for a wide range of applications:

- Microbial growth/MIC
- IC 50s/LD 50s
- Endpoint ELISAs/EIAs
- Cytoproliferation/cytotoxicity
- Colorimetric protein
- Kinetic ELISAs/enzyme assays
- Platelet aggregation
- Bacterial identification
- Clotting/clot lysis



*Trademark of Molecular Devices, Inc.

**Specifications subject to change

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#VERSAMAX - Tunable Microplate Reader and Operations Manual

#0200-6117 - Spectra Test ABSI Absorbance Validation Package (includes test plate)

Specifications**

Wavelength Range - 340–850 nm

Photometric Range - 0.000 to 4.000 OD

Wavelength Selection - Monochromator, tunable in 1 nm increments

Photometric Linearity (405 nm) - 0 to 3.000 OD

Wavelength Bandwidth - 2 nm

Photometric Accuracy (340–850 nm) - < ±0.006 OD ±1.0%, 0–2.0 OD

Wavelength Accuracy - < ±0.003 OD ±1.0%, 0–2.0 OD

Endpoint Read Time - 12 seconds

Temperature Range - Ambient + 4°C, to 45°C

Kinetic Read Time - 9 second minimum interval

Temperature Uniformity (Microplate) - ±0.5°C @ 37°C well-to-well

Dimensions - 22 cm (h) x 58 cm (w) x 38 cm (d)

Weight - 30 lb (13.6 kg)

SoftMax Pro Software Standard Edition - included with VersaMax Plate Reader

SoftMax Pro GxP Edition - sold separately. See page 5.5

SoftMax Pro 5 Standard Edition Microplate Data Acquisition and Analysis Software (included with the VersaMax Plate Reader)

SoftMax Pro 5 software has raised the bar for microplate data acquisition and analysis. SoftMax Pro 5 represents the most feature-rich release of this software.

New features include:

- Five parameter (5PL) logistic curve fitting
- Parallel Line Analysis (PLA) with observation weighting
- Over 120 ready-to-run assay protocols for instant results generation
- Native support for Mac OS X
- XML export and multiple destination AutoSave with new options
- Enhanced Windows Interprocess Messaging for better robotics/LIMS/SDMS integration
- Detailed printed headers and footers
- Faster file saving
- Dozens of other features and usability enhancements
- Full backwards-compatibility

SoftMax Pro 5 Software GxP Edition CFR 21 Part 11 Compliant

SoftMax Pro 5 GxP Edition provides regulatory compliance features to the market-leading microplate data acquisition and analysis package. Tools for speeding software validation are also available.

Expanded support for GxP and FDA 21 CFR Part 11 compliance include:

- Optional Guest Logon at launch
- IP-based linking to User Accounts files
- Support for multiple administrators
- Remote administrative management of entire solution
- More administrative control over end-user permissions
- Automated offline use to protect against network outages
- TCP/IP-based hosting of User Accounts files

SoftMax Pro Software Validation Package

Features

- Specification for electronic signature, audit trail, and data integrity features
- Software development life cycle analysis
- Integration testing documentation
- Assistance in FDA 21 CFR part 11 compliance

The software validation package is designed to help you achieve GLP and GMP compliance by allowing you to validate the built-in calculations in SoftMax Pro software's menus and Group table column formulas, as well as your own custom formulas. The validation package includes data sets used to validate SoftMax Pro's calculations, instructions for creating custom data sets to validate custom calculations, ASCII text files, Microsoft Excel® spreadsheets to check the results of SoftMax Pro calculations, some guidelines for IQ/OQ/PQ validation, and a manual containing extensive documentation. Validation packages are available for both Windows® 2000/NT/XP Pro and Mac OS® operating systems.

#VERSAMAX	-----	VersaMax Reader with SoftMax Pro 5 Standard (4 licenses)
#0200-6209	-----	SoftMax Pro 5 standard (non-21 CFR Part 11, 4 additional licenses, First 4 licenses included w/reader)
#SMP52-GXP-5UL	-----	SoftMax Pro GxP (5 user license, compliant)
#SMP52-GXP-10UL	-----	SoftMax Pro GxP (10 user license, compliant)
#SMP52-GXP-15UL	-----	SoftMax Pro 5.2 GxP (15 user license, compliant)
#0200-6117	-----	Spectratest ABS1 validation test plate
#VPMD	-----	VersaMax validation protocol
#SMP52-VAL-PAK	-----	SoftMax Pro Validation Package (For SMP52-GXP-5UL)
#9000-0938	-----	Adaptor, Serial to USB
#S9200-0006	-----	Training-Initial Life Science

Spectra Test ABS1 Absorbance Validation Package

Qualify the absorbance performance of the VersaMax Microplate reader by testing the specifications that are absolutely critical to compliance. Eight different automated tests are provided:

- Absorbance accuracy (linearity)
- Precision (reproducibility)
- Stray light
- Wavelength accuracy
- Wavelength repeatability
- Ultimate dark (0% transmittance)
- Optical alignment
- Baseline noise

ELx808™*

Incubating Microplate Readers

The ELx808™ Incubating Microplate Reader is used to perform endotoxin and glucan testing using the chromogenic or turbidimetric methods. The detection limit depends on the protocol and reagent employed. Sensitivity as high as 0.005 EU/mL may be achieved with Pyrochrome® lysate, Chromo-LAL lysate, and Pyrotell®-T lysate. Gen 5 software is sold separately. See page 5.7.

This multi-channel incubating reader offers excellent temperature uniformity through independently monitored natural convection heaters and 4-zone temperature control for improved reproducibility in kinetic enzyme reactions.

Additional Features

- Programmable and variable shaking speed
- End-point, Kinetic and Well-Scanning capabilities
- On-board data analysis, including curve-fitting



#PPS04 ----- -ELx808 Incubating
 Microplate Reader and
 Operations Manual

System Specifications

Computer Required ----- Intel® Pentium® 4 PC or newer;
 2.4 GHz Windows® XP SP2 OS;
 1 GB RAM (if stand alone);
 40 GB HD, 800 x 600, 256 Color Monitor;
 serial port or compatible USB adaptor required
 (for reader communication)

Capacity ----- -96-well plates

Power Requirement ----- 100–240 V, 50/60 Hz

Fuse ----- 120 V: 1.5 amp slo blo
 240 V: 0.6 amp slo blo
 5 x 20 mm

Light Source ----- Tungsten halogen bulb

Filter Configuration ----- -340, 405, 490,
 540 and 630 nm

Dimensions ----- 15.5 w x 8.75 h x 16 d in.
 (39.4 x 22.2 x 40.6 cm)

Weight ----- 30 lbs. (13.6 kg)

Temperature Range ----- -4°C above ambient
 to 50°C, well-to-well
 uniformity ± 0.5°C

Data Interface ----- 25-Pin RS-232 port

Data Transmission Format ----- ASCII character
 strings, 9600 baud

Registration ----- CE Mark, ETL Mark
 for UL3101-1, CAN/CSA
 C22.2 No. 1010.1,
 Conforms to IEC 1010-1

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*Trademark of Bio-Tek Instruments, Inc.

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Gen5™ Secure Software*

Designed by engineers focused on microplate instrument technology for microplate users, Gen5™ works the way you do. Gen™ Secure Software is customized 21 CFR Part 11 compliant software for the ELx808™ Incubating Microplate Reader.* Experience for yourself more efficient workflow with Gen5's logical interface designed to easily flow from reading parameters to plate layout, to data reduction, to fully customized publication ready reports. Or, export data directly into Excel® with a "Quick Export" button. Gen5's intuitive design will be evident in increased laboratory efficiency.

Validation Protocols

Validation Protocols provide the end user with a comprehensive set of integrated documents to guide them through the system validation process. A Validation Plan outlines the tasks and documentation required to perform the validation. A Requirements Specification, the foundation of the validation process, clearly delineates the system's required functions and expected performance. Detailed instructions guide users step-by-step through the IQ/OQ, and PQ processes. Stress Test procedures are included as well as Change Control and Maintenance guides. A CD containing the protocol files in Microsoft® Word format allows users to edit the documents to meet their company's specific validation requirements. A Validation Protocol Package is available for the ELx808 Incubating Plate Reader with Gen5™ Secure Software.

- #PPS04 ----- ELx808 Micro Plate Reader
- #ELXP ----- Universal Test Plate.
For ELx808 Micro Plate Reader.
- #Gen5Secure-----Gen5 Secure Software.
Compliant, Microplate Software;
Data collection and analysis.
- #Gen5DIAG----- Gen5 Diagnostic Utility.
Options for automated testing,
result output and archive functionality.
- #5320500 ----- Gen5 Installation Qualification Package.
Packages include thorough procedures
to allow a user to perform installation.
- #PQPE----- Product qualification package, ELx808

*Trademark of Bio-Tek Instruments, Inc.

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