

## Letter From the President



*Dear LAL User:*

*At the end of 2002 Associates of Cape Cod, Inc. (ACC) introduced what we believe to be the first LAL-dedicated software to be fully Part 11 compliant. Pyrosoft™-11 was conceived and designed by ACC scientists to be not only Part 11 compliant, but also meet the functional requirements for the kinetic turbidimetric LAL assay. Although laid out on the same lines as our previous software packages: Pyros®, Pyros Kinetix™, and Pyrosoft™-MP, Pyrosoft-11 is completely new in keeping with the latest recommendations for producing Part 11 compliant software (see ACC's White Paper on Part 11 Software). Unlike other programs on the market that use so-called "patches" to lend functionality, e.g. electronic signatures, to existing software, Pyrosoft-11 was developed new, from the ground up. Our Pyrosoft Development Team (PDT) oversaw all stages of development. Although ACC took advantage of an external company to write the code, much of the actual work was done by their staff on site at our facility. Final testing was all done in-house using our own Information Systems people who were also part of the PDT. Finally, all the manuals and the actual CD's containing the program, were and will continue to be, produced in-house. ACC feels that only through this level of control can our clients be assured of a quality, fully compliant product.*

*For the technical part of this Update, I have asked Dr. Jack Sloyer, ACC's Director of Research and PDT leader to discuss the various attributes of Pyrosoft 11.*

*Sincerely,*

*Thomas J. Novitsky, Ph.D.*

## TECHNICAL REPORT

### The Pyrosoft™-11 Solution

*By Jack Sloyer, Ph. D.*

The Pyrosoft-11 program to measure endotoxin has been designed with the end user in mind assuming that compliance is a major priority. Features have been incorporated that are required by 21 CFR Part-11 regulations to maintain and track data integrity and accuracy in addition to preserving and/or enhancing user friendly features of earlier versions.

#### **Pyrosoft-11 features:**

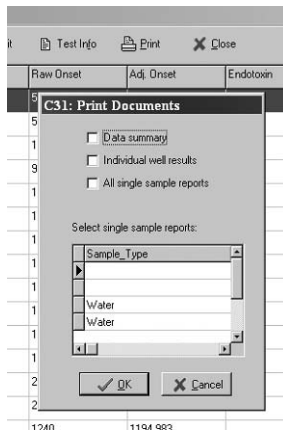
- ⇒ Differential access for administrators, managers and technicians
- ⇒ Unique electronic signatures with time-stamped expiration
- ⇒ Program timeouts forcing re-authentication of user
- ⇒ Raw data accessible and protected
- ⇒ Multiple report forms
- ⇒ Auditable tracking of report editing
- ⇒ Audit trails tied to system, assay and user
- ⇒ Trending reports.



## Part 11 Mandatory Requirements Include

### Accurate Record Generation

The rule states that accurate records must be generated in both human readable and electronic form suitable for inspection, review, and copying by the FDA. Pyrosoft-11 has several approaches (shown at right) which facilitate this requirement from the Data Analysis portion of the program. Reports are generated from raw data. However, auditors wishing to see the raw data file have it readily available in Pyrosoft-11.



CIA: Analyze Data - TAP ES2

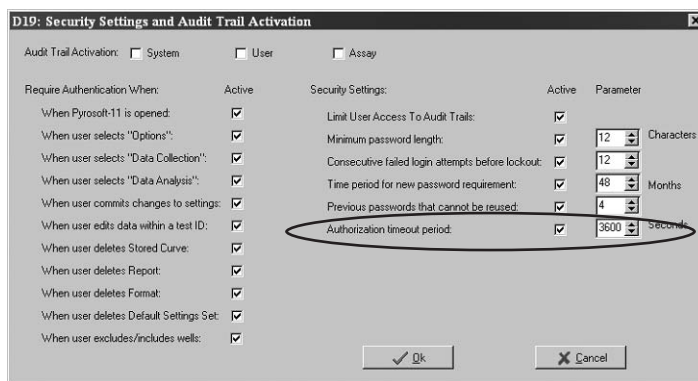
Well	Description	Dilution	Raw Onset	Adj. Onset	Endotox
1	Negative Control		5340		
2	Negative Control		5340		
3	Standard Control		1000	965.554	0.945
4	Standard Control		990	976.311	0.9
5	Standard Control		1090	1066.258	0.615
6	Standard Control		1100	1047.85	0.663
7	Standard Control	0.25 EU/mL	1350	1331.175	0.235

CIA: Analyze Data - TAP ES2

Well	Description	Spike conc.	Raw Onset	Adj. Onset	Endotox
1	Negative Control		5340		
2	Negative Control		5340		
3	Standard Control	1	1000	965.554	0.945
4	Standard Control	1	990	976.311	0.9
5	Standard Control	0.5 EU/mL	1090	1066.258	0.615

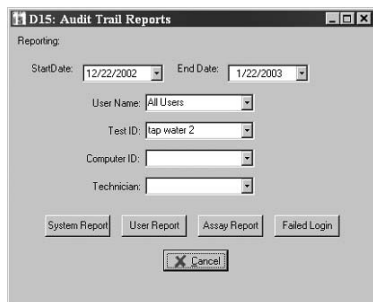
### Program Timeouts

Once logged into the system, there must be a provision for re-authentication after a period of inactivity. The administrator has the authority to change the timeout period and/or its activation. The maximum timeout period is one hour (3600 seconds). Any changes are recorded in the audit trail.



### Audit Trails

Changes to a record are recorded. These changes include, for example, editing, login problems, etc. The User can select different reports as well, such as, a System Report, a User Report, an Assay Report, or a Failed Login Report. To the right is the initial screen in which a User selects criteria to be examined. For example, an administrator can track a Failed Login and report the status of that User. Also shown is an Assay Audit Trail Report in which a well was excluded.



D18: Assay Audit Trail Report 1/21/2003 3:14:56 PM

Report Start Date: 1/22/2002 Report End Date: 1/22/2003

Trail Entry Date/Time Of Audit	Username	Test ID	Primary Analysis Calc. and Values Pre-change	Primary Analysis Calc. and Values Post-change	Comments
1/9/2003 2:32:40 PM	ADMIN	Tap Water 3	False	True	Changing Exclude value for well 10

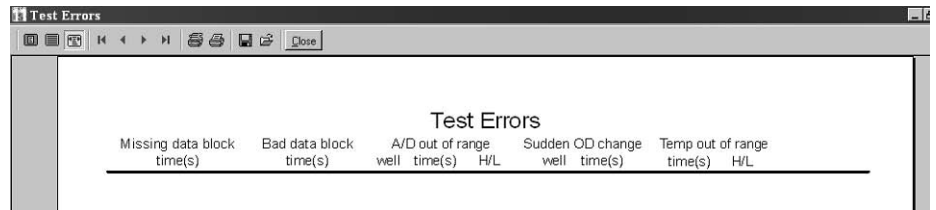
D20: Failed Login Report 1/21/2003 2:56:34 PM

Attempted Login Date/Time	Username	Computer ID	User Locked Out?
1/6/2003 3:05:43 PM	ADMIN	IBM1006	False
1/21/2003 2:31:17 PM	admin	IBM02012	False
1/21/2003 2:55:43 PM	inf	IBM02012	True
1/21/2003 2:56:12 PM	inf	IBM02012	True



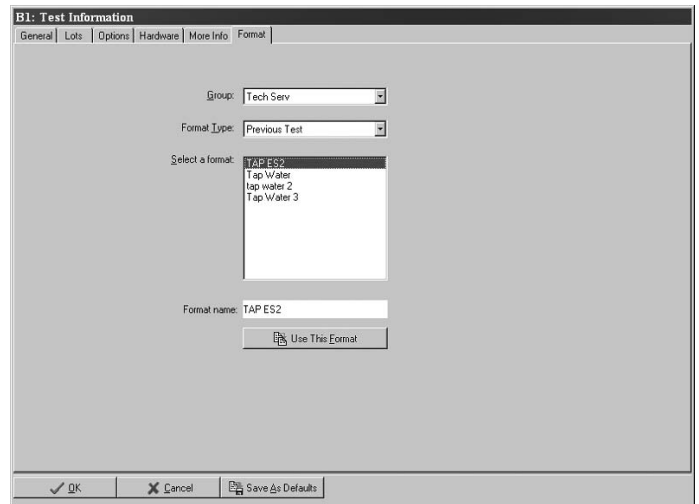
## Event Logging

This refers to alerts and errors that may happen. These events are recorded in the Audit Trail and also in an Error Report. Errors are reported in a Test Errors section whereas changes are reported in the Audit Trail. Test Error categories are shown to the right. Test Errors, if any, also appear in a Trending Report.



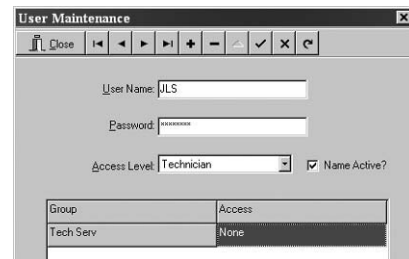
## Validation Rules

Key aspects can include: restricting a range of values where appropriate, e.g. default settings or previously entered values. In Pyrosoft-11, a User can define a series of settings which can be named and repeatedly retrieved for use when conditions warrant. Therefore, the chances of making errors when entering test parameters is minimized, if not eliminated completely.



## Controls for Electronic Signatures

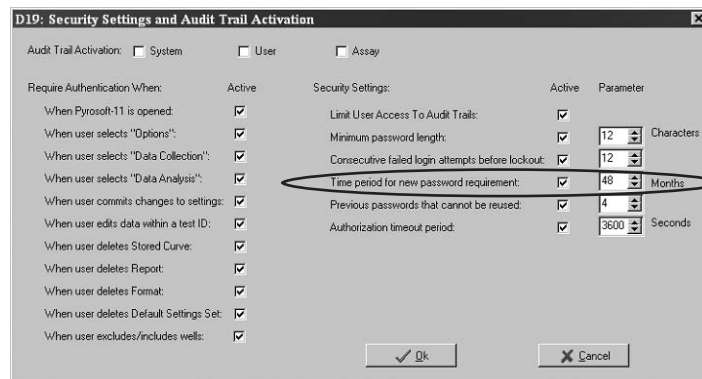
User ID and Passwords in conjunction with relation to a test Group or Test ID are stored. When analyzing and reviewing data, only an Administrator or a valid member of the respective data group who has either Read and/or Write authorization (set by the administrator) has access to the respective report and any edit capabilities (if write authorization is granted). In addition, any editing changes, are reflected in the audit trail, which identifies the Test, the User, and the changes which were made. A user may be Active and may have his/her privileges restricted from Read/Write to Read to None (as is shown).





### Password Expirations

Pyrosoft-11 has a setting which can be defined by the program administrator. The maximum time allowed for a password is 48 months.



### Notes for the Future

The features described above are representative examples of how Pyrosoft-11 attempts to aid manufacturers in the production and release of FDA regulated products subject to endotoxin testing statutes requiring Part-11 compliance. Associates of Cape Cod, Inc. will continually investigate ways to improve and upgrade its software not only to comply with new regulations but also to facilitate compliance for its users. Feedback is welcomed and every attempt will be made to include customer suggested enhancements,

Pyrosoft-11 requires computer power which was not available in 1997 at the time of 21 CFR-Part-11 implementation. One of the early requirements was for Pyrosoft-11 to operate on several Windows operating systems including Windows NT, 2000 and XP. In order to get this necessary product to our customers as quickly as possible, it was tested using Windows XP. Testing is currently underway for earlier operating systems but we still recommend using Windows XP.

A look into the near future reveals the addition of microplate reader capabilities to Pyrosoft-11. The intent is to provide options in choosing equipment without having to validate different software packages, depending on which equipment is used. As with the current version of Pyrosoft-11, all the Part-11 data integrity, auditing, and electronic signatures are preserved. In addition, other features such as trending remain intact and will be extended to include data generated by a microplate reader.

Look for news on Pyrosoft-11 upgrades and applications in future LAL-updates as well as on our website: [www.acciusa.com](http://www.acciusa.com)



## First Crabs Bled in New Facility

On January 15, 2003 Associates of Cape Cod, Inc. (ACC) staff conducted the first horseshoe crab bleeding in its new facility. Although this bleed was conducted as part of the validation process necessary to secure a facility license, it was a complete success. It also demonstrated our ability to bleed crabs the year around. Formerly our crab bleeding was confined to the late spring and summer months due to the size and design of our old facility and our suppliers. Our new facility, coupled with new crab suppliers and holding tanks, will maximize our crab bleeding capacity and virtually eliminate the possibility of ACC running short of LAL.



## Order Information

### Pyrosoft™-11

- #SPS11 Pyrosoft-11 Software with Manual
- #VPPS1 Pyrosoft-11 Validation Protocol Documents for Pyros Kinetix
- #VPPS2 Pyrosoft-11 Validation Protocol Documents for LAL-5000
- #PSV01 Pyrosoft-11 Verification Package

### Pyros Kinetix™ and Accessories

- #PKX02 Pyros Kinetix Incubating Kinetic Tube Reader
- #WPKX1 Extended Warranty for Pyros Kinetix
- #CAL02 Calibration for Pyros Kinetix

### ELX808 Microplate Reader and Accessories

- #PP04 ELX808 Incubating Microplate Reader
- #PT08 Lamp for ELX808
- #ELXP Universal Test Plate for ELX808 Incubating Microplate Reader

### Turbidimetric Lysate

- #T0051 Pyrotell®-T - Multi-test (approx. 50 tests) 5ml/vial

### Chromogenic Lysate

- #C0031 Chromo-LAL (3.2ml/vial)
- #C0060 Pyrochrome® - 60 Test Kit
- #C0120 Pyrochrome® - 120 Test Kit
- #C0180 Pyrochrome® - 180 Test Kit
- #CD060 Pyrochrome® - 60 Test Kit with Diazo-Coupling



**MARCH 2003**

**March 17-18**

**Spring PDA**

*Paradise Point Resort  
San Diego, CA  
Booth #302*

**APRIL 2003**

**April 29-May 1**

**LAL Training Courses**

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and Laboratory Training  
Sheraton Chicago Northwest  
Arlington Heights, IL*

**JUNE 2003**

**June 17-19**

**LAL Training Courses**

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and Laboratory Training  
ACC Falmouth Facility  
Falmouth, MA*

**JULY 2003**

**July 15-17**

**LAL Training Courses**

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**For customer service:  
call (800) LAL-TEST or (508) 540-3444.**

**For technical service:  
call (800) 848-3248 or (508) 540-3444.**

**Please visit our website! [www.acciusa.com](http://www.acciusa.com)**

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*Creating New Horizons in Endotoxin Testing*

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