

PyroMon™ Pro



*High
performance
pyrogen test
system*

PyroMon™ Pro Automatic Pyrogen Test System



Stay Safe & Compliant

The PyroMon Pro offers a simple way to document product safety. The reports generated by the PyroMon Pro, documents that the products being used are in compliance with current regulations. There are numerous advantages to using an automated system, as it simplifies operating procedures, saves time and keeps costs under control.

PyroMon™ Pro 40 channel module

Validated to Comply with GAMP & FDA 21 CFR Part 11

To ensure integrity and reliability, the PyroMon Pro system is validated following GAMP and is FDA 21 CFR Part 11 compliant. The software makes use of a SQL database that keeps track of animals, pharmacopoeias, samples, dosages, weights, test results, etc. The information is easily accessible and users stay up-to-date on the animals in quarantine, completed sham tests and animals ready for pyrogen testing.

Relay to ethernet connection

It is possible to extend the alarm functionality of PyroMon Pro software by connecting an external relay for ethernet connection. By using this Relay the unfortunate situation of having one or more slipping probes, which activates an software alarm condition, can be detected and signal transferred to an audible / visible alarm signal box for easy and quick respond and correction from operator. The programming and setup of relay functions is handled by the Control Center in PyroMon Pro software.



Automatic Weight Detection

The PyroMon Pro system can be directly connected to a scale, making it easy to keep track of the test subject's weight. When the scale is connected, the animal's weight is automatically registered in the database. The software also includes an Animal history log, which shows the current weight as well as any previous recordings with time stamps.



Feature	Benefit
40 Channels (1 x 4 + 3 x 12 sensor arrays)	Can be expanded to have up to 120 channels
A sample rate of 1 sec. to 24 hours	Fast sample rates for improved resolution & evaluation
8" soft touch panel	Displays process mode & real-time data as a table or graph
Aluminium housing	Durable
Built-in 8-hour battery	Backup in case of power failure or electricity being unavailable
512 MB Internal Memory	Can sample up to 1.1 mill data points
Cabinet size (3.0 kg/6.6 lbs.)	Easily portable
Cabinet noise level	Very low / no fans
Premium grade thermocouples	Certified accuracy of +/- 0.1°C
Smart USB connector with ID and cold junction compensation	Calibration offsets travel with the thermocouple (saved within USB)
USB and Ethernet Network	Fast and reliable data transmission / Compatible with most PC's
Windows compatibility	Works with WIN 7, 8 & 10
Scale Interface	Automatically registers data
Template Built Software	Preconfigured pharmacopoeias e.g. USP-NF, ph. EUR, JP, KP and BP
IQ/OQ protocols	Complies with FDA requirements
User calibration	Automatic execution for time saving
Database	Full traceability of animals and test results
Compliance	FDA 21 CFR Part 11 / International GMP standards

PyroMon™ Setup - Step by Step

1. Define the Preparation setup and appropriate Run.
2. Create a session using the toolbar or activation Icon on the PyroMonSuite desktop.
3. Choose a configuration from the list of available PyroMon modules and select the appropriate run(s).
4. The sensor link list provides information regarding which animal ID is linked to which sensor ID. This can be obtained and checked.
5. Once all animals are assigned, the data is saved and a session can be started.
6. When the session is finished, PyroMon Pro reports are automatically generated with a clear pass/fail criteria according to the setup parameters.



NaCl 0.9% - DER-EUR-PH 8.5				
Total test result: Passed				
Dose	10 ml			
Pre Test Duration	00:01:12			
Injection Phase Duration	00:00:12			
Main Test Duration	00:05:00			
Data Points				
Type	Time	1	2	4
Pre test started	09:41:49	39.84°C	39.83°C	39.82°C
Read Point	09:42:01	39.84°C	39.84°C	39.81°C
Read Point	09:43:01	39.87°C	39.85°C	39.83°C
Injection started	09:43:01	39.87°C	39.85°C	39.83°C
Read Point	09:43:13	39.85°C	39.84°C	39.83°C
Injection ended	09:43:13	39.85°C	39.84°C	39.83°C
Read Point	09:44:13	39.88°C	39.87°C	39.85°C
Read Point	09:45:13	39.89°C	39.86°C	39.83°C
Read Point	09:46:13	39.88°C	39.87°C	39.84°C
Read Point	09:47:13	39.89°C	39.86°C	39.83°C
Read Point	09:48:13	39.89°C	39.88°C	39.84°C
Main test ended	09:48:13	39.89°C	39.88°C	39.84°C
Points used for calculation are marked with bold				
Control Temperatures				
Animal		1	2	4
Control temperature		39.85°C	39.84°C	39.82°C
Max temperature		39.91°C	39.90°C	39.87°C
Min temperature		39.85°C	39.84°C	39.81°C
Response		0.06°C	0.06°C	0.05°C
Criteria				
Name	Total Temperature Change			
Criteria	Passed			
Repeat value	1.15°C			
Fail value	2.65°C			
Animal	N/A			
Temperature	N/A			
Time	N/A			
Animals Required	N/A			

PyroMonSuite™ Software

PyroMonSuite™ Software

The PyroMonSuite software, in conjunction with the PyroMon Pro equipment, offers a complete system for Pyrogen tests in accordance with the demands from the pharmacopeias (USP-NF, ph. EUR, etc.).

The system collects, analyzes, displays and then reports the results of pyrogen tests. PyroMon Suite has been validated in accordance with GAMP and developed to allow maximum operation flexibility. The software ensures security and compliance with all the relevant requirements that are stated in the pharmacopoeias. It delivers tamper-free documented evidence, making manual recording obsolete. In addition to this, the PyroMonSuite provides essential benefits for the operators and management, i.e. audit trails, animal database and password protection.

The system can also run different pharmacopoeia (as well as Sham Testing) at the same time. It can do so without wrongly injecting, due to the clear color touch display on which the injections are shown for every individual. It verifies that the individuals under quarantine cannot be used in analysis.

*Collects,
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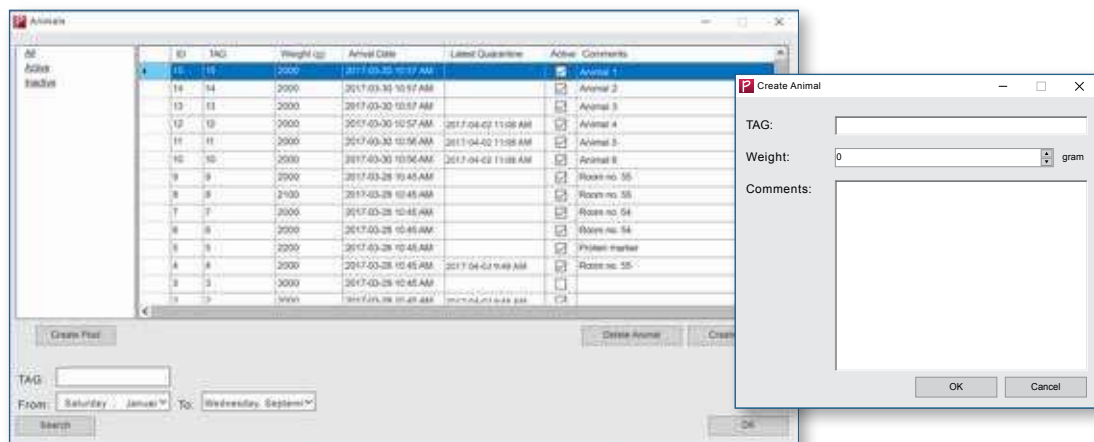
The display function includes a vertical and horizontal zoom option, single or multi-channel display and data output in the form of a list or graph. The report function enables the customization of generated reports.

The PyroMonSuite software can be used on different windows platforms, including Windows 10. It is also possible to install a setup server/client solution with a full audit trail.

The encrypted database is incredibly efficient at keeping data safe along every step of the way. The PyroMonSuite has a password option for logging in, which includes an access manager that enables customized user profiles. It also includes an audit trail, access points and FDA 21 CFR Part 11 compliance.

The software can handle up to 120 data channels/ animals at a time.

The handling of animals is made simple through the menu based software. By using the database, users can search for information regarding all previous entries as well as sort and/or group the content.



The Animal List Displays the Following

ID: Unique numbers that are automatically assigned to each animal for internal identification purposes.

TAG: The user-defined number or name of the animal.

Weight: The most recently recorded weight of the animal.

Arrival data: The moment the animal was added to the system.

Active checkbox: Indicates whether the animal is available for testing.

Comment: Contains additional user-defined information about the animals.

Creating/adding a new animal is simply done by entering the animal ID and Weight, followed by any applicable comments.

Methods

Method Information

Sham Test Information

Pre-Test Information

Main Test Information

Weight Information

Preloaded Pharmacopoeias

The PyroMon Pro system is preloaded with all pharmacopoeias (USP-NF, ph. EUR, JP, KP and BP). For full flexibility, it is possible to configure individual templates based on these preloads. The software will automatically analyze the recorded temperatures in relations to the pharmacopoeias and generate a report. The calculations and interpretations of the results are also done automatically, which eliminates the risk of human error and saves time.

A 'Method' is the PyroMonSuite's name for a specific pyrogen test, this is in accordance with the specific pharmacopoeia. The Methods window contains information regarding all the methods entered in the database. New methods and groups can also be added, sorted and searched according to individual needs.

By default, the list contains 5 methods:

- Japanese (JP-XVI)
- Korean (KP-X)
- North American (USP38-NF33)
- European (PH-EUR 8.5)
- British (BP 2013)

In addition to those, user-defined methods can also be manually added to the list. Each new method requires the following entry:

- General method info
- Sham test info
- Pre-test info
- Main test info
- Weight info

Automatic Calibration



The measuring capacity of the system is 120 highly accurate temperature channels. The total system accuracy is $\pm 0.1\text{ }^{\circ}\text{C}$ between 35 to 45 $^{\circ}\text{C}$. It is critical that the system measures correctly, which is why calibrations must be performed periodically.

The PyroMonSuite software includes a user calibration feature, which makes it possible to certify the system accuracy. The calibration runs fully automatically when using an Ellab Temperature Standard (ETS) in conjunction with a calibration bath.

The ETS and calibration bath have a direct interface to the PyroMon Pro system. Once the calibration is complete, the software generates a report that documents the ID number of the probe, reference value and possible deviation.

PyroMonSuite™ includes a user calibration feature

The screenshot shows the 'Calibration Setup' window with the following sections:

- Calibration Type:** Full-Automatic Calibration, Semi-Automatic, Manual Calibration
- Stability Criteria:** Fluctuation Band: 1.000, Fluctuation Time: 00 03 00, Holding Time: 00 20 00
- Pass Criteria:** Temperature Standard Fluctuation Band: 0.150, Channel Temperature Deviation (+/-): 0.30, Pass Time: 00 01 00
- Adjustment:** Enable Adjustment
- Templates:** Load, Save
- Temperature Standard Info:** Serial Number: 868602
- Calibration Points:** A table with columns for temperature and time. The table contains the following data:

Temp	Time
40.0	
37	
38.5	
40	

Buttons: Add, Remove, Insert, Clear.
- Set Point Tolerance (+/-):** 2.00





By combining state of the art hardware, software and accessories, the Ellab Solution is a perfect match for applications that require full documentation and FDA 21 CFR Part 11 compliance.

Ellab



Since the late 1940's Ellab A/S has been a leading manufacturer of process validation and monitoring systems used in the food, medical device and pharmaceutical industries.

Calibration Certifications and Service

Ellab maintains a complete calibration facility for annual certifications and service. Ellab A/S temperature, resistance, pressure and humidity calibration laboratory is accredited according to ISO 17025 by DANAK under registration no. 520. Service and maintenance contracts are available.

Training

Ellab Academy offers regular training courses for end-users. On-site individual training and equipment installations are also available through Ellab. Our Validation Consultants are available to assist you with IQ, OQ, and PQ procedures.



Validation Solutions

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